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**Risk Managing Food Safety
Comparing the Enforcement of Food Safety Regulation in the UK and Germany**

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KING'S COLLEGE LONDON

**RISK MANAGING FOOD SAFETY:
COMPARING THE ENFORCEMENT OF
FOOD SAFETY REGULATION IN THE
UK AND GERMANY**

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A thesis submitted to the Department of Geography of King's College London for the degree of Doctor of Philosophy, London, December 2016

Abstract

This thesis investigates the implementation of food safety regulation within the UK and Germany. The aim of the research is to assess and explain the extent to which risk-based approaches that are manifest in EU General Food Law, have been applied in each country. Drawing on extensive documentary and interview material, the thesis charts the history of food safety regulation in the UK, Germany and the EU, focusing on food safety enforcement at both national and local levels.

The thesis examines the factors shaping the way that ideas of risk have been operationalised within the enforcement of food safety regulation through three case studies. First, it uses the case study of food import controls to investigate the operationalisation of risk ideas at EU level, and in particular tensions between ideas of risk, hazard and safety. Second, the thesis examines how risk-based approaches to food safety enforcement are shaped by the concerns and interests of national and local authorities in Germany and the UK. Third, the thesis uses the case of food hygiene barometers to explore the key factors shaping and constraining the uptake of risk ideas in the UK and Germany.

The thesis concludes that despite the universalising claims for risk-based approaches to regulation, the case of food safety regulation demonstrates the normative, political and economic drivers shaping the differential uptake and use of risk ideas in advanced EU member states, even when regulation has been harmonised under EU law. The thesis builds on that conclusion to reflect on the future of risk-based policymaking in the field of food safety as well as contributing to wider ongoing social scientific discussion about the role of risk ideas within different polities.

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Abbreviations

AALA – Adventure Activities Licensing Authority
AFS – Assured Food Standards
ALARP – As Low as Reasonably Practicable
APHA – Animal and Plant Health Agency
APRA – Australian Prudential Regulation Authority
BfR – The Federal Institute for Risk Assessment
BIP – Border Inspection Post
BLL – German Federation for Food Law and Food Science
BMEL – The Federal Ministry of Food and Agriculture
BPA – Bisphenol A
BRC – British Retail Consortium
BVL – The Federal Office of Consumer Protection and Food Safety
BVLK – Federal Association of Food Inspectors (*Bundesverband der Lebensmittelkontrolleure*)
CAP – EU Common Agricultural Policy
CBA – Cost Benefit Analysis
CCP – Critical Control Point
CIEH – Chartered Institute for Environmental Health
CVED – Common Veterinary Entry Document
CVUAS – Chemical and Veterinary Investigation Office, Stuttgart
Defra – Department for Environment & Rural Affairs
DG SANCO (now DG SANTE) – Directorate General Health and Consumer Affairs)
ECJ – European Court of Justice
EFSA – European Food Safety Authority
EHO – Environmental Health Officer
EU – European Union (previously EEC – European Economic Community)
FBO – Food Business Operator
FDR – Federal Republic of Germany
FHRS – Food Hygiene Rating Scheme
FSA – Food Standards Agency
FVO – Food and Veterinary Office
GDR – Democratic Republic of Germany

GFL – General Food Law

HAACP – Hazard Analysis and Critical Control Points

IAB – Impact Assessment Board

IHK – Chamber of Industry and Commerce (*Industrie und Handelskammer*)

IMTA – International Meat Trade Association

LAV – National Consumer Protection Consortium (*Länderarbeitsgemeinschaft Verbraucherschutz*)

LFGB – Food and Feed Code

LMBG – Food and Consumer Goods Act

LÜKEX – Länderübergreifende Krisenmanagementübung Exercise (crisis management exercises)

MAFF – Ministry of Agriculture, Fisheries and Food

MHS – Meat Hygiene Service

MRL – Maximum Residue Limit

NHS – National Health Service

NMG – National Law on Food and Commodities (*Nahrungsmittelgesetz*)

NPM – New Public Management

NPRM – New Public Risk Management

OECD – Organisation for Economic Co-operation and Development

OFSA – Canadian Office of the Superintendent of Financial Institutions

OIRA – Office of Information and Regulatory Affairs

OMB – US Office of Management and Budget

OSHA – Occupational Safety and Health Administration

PAS – Primary Authority Scheme

PPA – Progressive Public Administration

QMS – Quality Management System

RASFF – Rapid Alert System for Food and Feed

RIA – Regulatory Impact Assessment

SEA – Single European Act

SFBB – Safer Food, Better Business

SME – Small and Medium-Sized Enterprises

SPS – Sanitary and Phytosanitary Agreement

SRA – Society for Risk Analysis

TDI – Tolerable Daily Intake

VIG – Federal Consumer Information Law (*Verbraucherinformationsgesetz*)

WKD – Economic police service (*Wirtschaftskontrolldienst*)

WHO – World Health Organisation

WTO – World Trade Organisation

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Chapter 1: Introduction

It is better by noble boldness to run the risk of being subject to half the evils we anticipate than to remain in cowardly listlessness for fear of what might happen.

Herodotus

According to Herodotus, these were the words of Xerxes, the ruler of the Achaemenid Empire, after he was counselled against an invasion of Greece in 480 BC. There were grave concerns over how he would sustain his army, but Xerxes was determined to take a risk, one that ultimately led to the failure of his Greek campaign. However, even though it is presented within a context of eventual failure, the above quotation from Herodotus conveys a sentiment that has been echoed throughout history; a soundbite reworked so many times that you don't need to look far to find a modern rendition. In order to live life to the full we should take risks, rather than cower in inactivity or indecision. It would be very difficult if we were halted by every conceivable risk we face. For example, we would not fare well if the risk of being run over stopped us from ever crossing a street. But risk cannot be wholly associated with negative consequences. Indeed, risk-taking is the great enabler to many – entrepreneurship is now synonymous with the notion of taking risks, as many successful businessmen and women will tell you in their rags to riches stories. So, do we actively take risks to (hopefully) encounter future benefits? Or do we avoid risks to keep our persons and our property safe? Experientially, it is clear that risk is ubiquitous within our lives. Crossing roads, eating food, doing (or not doing) exercise, investing money, giving birth; there is an element of risk in every action we take. We hear fanciful statistics about the risk of being hit by an asteroid, falling down a manhole or being struck by lightning... twice. Risk is a term that is at once understood, yet so pervasive that to fix upon one universally accepted definition may amount to folly. In 1987, the Committee on Definitions, of the Society for Risk Analysis (SRA), released a rather defeatist statement via the SRA newsletter:

After two years of work, in which its members were themselves unable to arrive at a single definition of risk, the Definitions Committee decided that it would recognize that different definitions are in use among the disciplines involved in risk analysis and risk management (SRA 1987).

To illustrate the point, the newsletter published thirteen definitions of risk.

With this brief scene-setting, we have a concept that can lend itself to ideas of danger (the risk of crossing the road) and/or possible benefits (risks and benefits of investing money in the stock market) and will therefore incite people to either avoid risk or embrace it (depending on their own personal risk “appetite”). And as risk is so ubiquitous, we must deal with it on a societal level, whether that be by setting speed limits in residential areas, or regulating the stock market to deter unscrupulous activity. One of a government’s most important functions will invariably be to decide whether to regulate (or how much to regulate) against an array of risks that may affect its citizens.

The tools of risk analysis have been central to the determination of risk. The development of statistical models for calculating the level of risk that the public may face has its roots in the scientific revolution of the 16th century, with the explosion of international trade and the establishment of precursors to modern insurance companies. Now, risk has increasingly become the defining characteristic of modern regulatory action, rather than a factor to be considered. Modern governance terminology reflects this, with “risk-based” approaches to entire policy domains. It is no longer a case of the regulation of risks, but rather, the risk of regulation.

1.1 Risk-based regulation

The move from the regulation of risks, to the risk of regulation, is epitomised by risk-based regulation becoming an overarching logic of regulatory action. By applying the frameworks of probability and impact to ascertain risk, regulatory interventions can be optimised. Furthermore, risk-based regulation is predicated upon the principle that it is not possible to regulate down to zero harm. There has therefore been a move away from the simple dichotomy that a harm is either safe or not safe, as acceptable levels of risk are set. The overall goal of regulation is now the recognition of limited enforcement resources. These resources should be proportionally allocated to ensure the compliance of those regulated, to the standards set.

With this increasingly critical role that risk plays within governance, risk-based regulation has been applied across a diverse set of policy domains, from financial services to health and

safety; food safety to flood defence. Governmental organisations that claim to rely on risk-based regulation include the US Office of Management and Budget (OMB), World Trade Organisation (WTO) and the Organisation for Economic Co-operation and Development OECD (OECD 2010). The European Union has also been championing the use of risk-based regulation, especially in the fields of food safety and health and safety at the workplace. The emerging use of risk-based regulation across supranational organisations suggests that it also plays an increasingly harmonising role across constituent member states. Whilst it has been mentioned that risk-based approaches have been utilised in dealing with societal risks, they have also been used in internal governance arrangements, dealing with institutional risks. The regulation of risk is no longer simply concerned with mitigating harms, but with internal organisational risks that come from regulatory interventions, such as the reputational risk incurred from attempting to regulate a harm over which there may be heightened public risk perceptions. Finally, it is not just public institutions that have been driving risk-based approaches. In fact, the drive for the application of risk-based thinking largely comes from the private sector.

1.2 Food safety

The policy domain of food safety provides a compelling choice for research into risk-based approaches. Food safety is a traditional public bad, in that it is an area of policy where public expectations point towards a standard of absolute safety. There can be few policy domains that demand such careful consideration of both existing and emerging risks as the domain of food safety. As Nestle (2003) asserts, “who could possibly not want food to be safe? Consumers do not want to worry about unsafe food and do not like getting sick”. Indeed, more often than not, we expect the food we consume to be safe and expect regulatory agencies to ensure such safety (Hawthorne 2005). When food safety incidents do occur, such as the BSE crisis that spanned from the 1980s to the turn of the 21st century, the 2008 melamine milk scandal and the 2011 *E. coli* outbreak in Germany, they tend to make front-page headlines and generate acute social amplifications of the risks (see Pidgeon, Kasperson et al. 2003). Past experiences of food safety incidents have led to deep regulatory changes, as entire institutions have either been closed down or radically altered in their approach to guarding against food hazards (Löfstedt & Vogel 2001). A diverse spectrum of powerful interest groups guarantees that the spotlight is firmly fixed upon every regulatory aspect of the control of food safety. Finally, the scale of global food business, which accounts for a

significant portion of global annual trade (total exports of global food products were valued at \$1,456,682 million in 2013), ensures that industry not only takes an active role in the regulation of food safety, but in many instances, takes regulatory responsibility (Banati 2003, Hatanaka, Bain et al. 2005). This enforced self-regulation by businesses is becoming increasingly prevalent (Fairman and Yapp 2005). Indeed, it can be seen as indicative of environmental health regulation generally, as regimes based upon strict enforcement and deterrence, usually referred to as command and control regimes, are increasingly being viewed sceptically by decision makers (Garcia Martinez, Fearn et al. 2007).

These new regulatory approaches, which are centred on the risk of non-compliance by food businesses to standards set, are anchored by the principles of risk-based regulation. However, the heightened public perception of food safety, coupled with an all-encompassing EU General Food Law that states that no unsafe food shall be placed on the market, reveals important distinctions between approaches that rely on the regulation of a harm, or hazard, and approaches that first calculate the probability and impact of that harm, through risk-based decision making. Food safety therefore offers an intriguing case study, with the regulation of this policy domain effectively at the crossroads of regulating hazard, or regulating risk.

1.3 A comparative analysis of the UK and Germany within a European context

This thesis will compare the enforcement of food safety practices within the UK and Germany, to ascertain the extent to which food safety regulation is, or can be, risk-based. It could be expected that food safety regimes would be quite similar across the UK and Germany. Both are western, industrialised nations and long-term members of the EU. Both countries openly profess to a strong risk-based approach to food safety (for the UK see Hutter and Amodu 2008; for Germany see BfR 2011). The EU has championed the use of risk-based regulation across its Member States, and risk analysis is enshrined within the General Food Law (GFL). Conveniently, approximately 98-99% of the food law of both countries is founded upon EU food law. As such, both of these countries should exhibit food safety regimes that are consistent with EU legislation. Finally, due to the salience and perceived importance of the food safety domain within both countries, it is not expected that either would diminish the significance of ensuring the safety of its food supply, especially in the wake of recent high-profile food incidents (see Chapter 4). Neither would both countries wish to miss out on the economic incentives of the global food trade. However, research into these

two countries allows for investigation into the different ways in which risk-based regulation is applied in the UK and Germany, and what any differences mean for the application of risk-based regulation more generally.

1.4 The universality of risk-based regulation

While there is a regulatory drive at the European level to increase levels of harmonisation in food safety through risk-based approaches, there has been debate as to whether risk-based regulation does indeed offer universal and centralising approaches, which may negate a range of national and/or local political, cultural and historical contexts.

While scholars have shown that risk-based approaches are becoming increasingly prevalent across a range of policy domains – from health and safety (Demeritt et al. 2015) to flooding (Krieger 2012), financial services (Black 2009) to higher education (Griffiths 2016) – there is debate over the extent to which risk-based approaches offer universal solutions to policy issues within different national contexts. To what extent does the “pervasiveness of risk-based routines in practices of government and in most areas of life” (Krieger 2012) translate to harmonising pre-existing diverse regulatory arrangements?

The idea behind the universal nature of risk-based regulation is a simple one that has gained increasing traction in recent years. The notion is that governments should direct their limited resources to the worst, most likely problems. Such a rationale can be applied across policy domains and local and national boundaries. This universalising rationale chimes with an ontological perspective of risk itself, as some authors have argued that globalized modern risks break down the barriers between different actors in society, as previously separate communities face the same risk. Beck (1992) defined this phenomenon as, “The end of the ‘Other’, the end of all our carefully cultivated opportunities for distancing ourselves... with the end of nuclear and chemical contamination”. However, Lupton (1999) argues that investigation into how risk discourses operate within different contexts refutes the ‘otherness’ that Beck defined. Lupton argues that in focusing on the universalising language of risk, many academic discussions ignore how differing groups respond to risk, representing the risk actor as “lacking a gender, age, ethnicity, social class or sexual identity”. Indeed, the utilitarian framing of risk as probability multiplied by consequence can collide with national political philosophies of governance interventions.

This debate on the universality of risk is especially pertinent within the EU context, where Member State regulatory regimes can be heavily reliant on standard setting at EU level, as is the case with food safety. However, scholars have highlighted a range of factors that might contribute to national administrations filtering out or biasing responses to external regulatory pressures. Studies into national styles of administration within EU Member States show that on the one hand, policy divergence is caused by institutional contexts and developments. Whilst on the other hand, increasing supranational harmonisation does lead to policy convergence at a national level (Knill 2001). While the picture is far from clear, such studies have pointed to a diverse range of factors that might shape the extent to which there may be policy convergence or divergence across Member States. These include regulatory path dependencies, differences in regulatory and legal infrastructures, variances in norms, behaviours and local/national identities of different actors, and even the use of language. To take one important variable as an example, Katzenstein's identification of 1980s West Germany as a semisovereign state is predicated upon different institutional arrangements from those within the UK and US (Katzenstein 1987). While 1980s Britain and America were embroiled in pronounced ideological shifts in policy, the corporatist arrangement and spread of power across institutions led to incremental policy approaches based on cooperation, rather than entrenched ideological opposition.

Research into Europeanisation indicates that power does not purely reside either within the sovereignty of a Member State on the one hand, or that of the European Union on the other. Instead Member States pass policy functions onto EU institutions, while devolving others to either national or local administrations. As Katzenstein (1997) concludes, "power relations do not add to a fixed quantity that either resides in national states or gets transferred to a supranational center of decision making". Such power relations between Member States and the EU are constantly evolving. With the development of the EU, and the creation of a single market, shared standards have become the bedrock for greater European integration and supranational governance (Borraz 2007). However, as was made clear in the UK's 2016 referendum on membership of the EU (Rozenberg 2016), sovereignty has become a highly politicised weapon that has affected the EU's capacity to act as a supranational governing body.

Therefore, scholarly insight into Europeanisation indicates a fluid scale between the harmonising influence of European institutions, and the countervailing presence of local and national factors. However, the EU's apparent drive towards implementing risk-based approaches within the highly centralised policy domain of food safety should help identify some key factors that may challenge the harmonising expectation of risk-based regulation across Member States.

1.5 Research Questions

This research aims to understand the extent to which risk-based regulation features within European regulatory regimes. As such, it is hoped that by selecting the UK and Germany, the challenges facing the implementation of risk-based regulation will be highlighted across differing social, cultural, legal and economic landscapes. An overview of the role that risk plays in the German, UK and EU food safety domains, coupled with the investigation of specific case studies, will allow for a detailed assessment of regulatory pathways, and will clarify the extent to which risk-based approaches are a feature of enforcement practices. To understand the pervasiveness of risk-based regulation in the food safety domain, the following research questions have been set:

- 1) Does the implementation and enforcement of risk-based regulation differ across local, national and supranational domains?**
- 2) If differences exist, then why is this the case?**
- 3) What are the implications for developing a common understanding of what it means to be “risk-based” within the context of food safety?**

To answer the research questions set, this doctoral research aims to investigate the food safety regime within a supranational, national and local context. Specifically, the thesis will look at enforcement practices and cultures, as an indicator of the efficacy of implementation of risk-based approaches. To ensure the research is informed by the current literature, Chapter 2 will plot the rise of risk-based regulation in modern society, through its historical development, as well as present some of the key constraints and drivers to the application and enforcement of such a regulatory approach. With the complex nature of the EU's food safety

regime, as well as the proliferation of sub-regimes at a supranational and national level, Chapter 3 provides a rationale for case study choice, as well as methodological framework for the research. Chapter 4 provides historical background to the regulation of food safety across the EU, Germany and the UK, to provide context to the differing cultures and practices that have existed within the countries under discussion. As the food safety domain is highly centralised within the EU, the thesis will then go on to investigate the EU's approach to risk-based regulation, and its attempt to champion developments within this area, signified by a sub-regime that is closely regulated by the EU – food imports (Chapter 5). The thesis will then analyse national and local approaches to enforcement practices UK and Germany, and investigate the extent to which these practices allow for the implementation of risk-based approaches (Chapter 6). Finally, the implementation of food hygiene barometers within the UK and Germany will be assessed, as these are publicly available risk scoring systems that aim to communicate the level of food hygiene risk found in local food businesses (Chapter 7). The control of food hygiene barometers is one of the few areas within food safety regulation that isn't mandated by EU regulations, so will help to indicate national and local approaches to the management and communication of risk. Finally, an overarching discussion of the three empirical chapters will see how the flow of risk-based regulation is affected as it is applied from the EU standard setting level, to national and local enforcement within the two countries under investigation (Chapter 8), as well as concluding by offering an appraisal of the challenges faced by implementing harmonised and consistent risk-based regulation across member states within supranational policy regimes.

Chapter 2: Risk-based Regulation

Every man has a right to risk his own life in order to preserve it. Has it ever been said that a man who throws himself out of the window to escape from a fire is guilty of suicide? Has such a crime ever been laid to the charge of him who perishes in a storm because, when he went on board, he knew of the danger? Jean Jacques Rousseau

The above quotation comes from Rousseau's musings on the right of life and death in his collection of works, entitled *The Social Contract or Principles of Political Right*. Here Rousseau grapples with how an individual can confer the right to end his/her life to the Sovereign (Head of State), when that individual does not have such a right in the first place. The quotation in question forces the reader to consider that the concept of taking one's own life may not be as straightforward an affair as it would seem. No doubt taking a journey by sea in Rousseau's lifetime, the 18th century, would have been a hazardous and even perilous endeavour. But should a sailor who perishes in a storm be seen to have taken his own life, because he was equipped with knowledge of the likelihood of such a storm occurring? Highly unlikely. Furthermore, should that same sailor take responsibility for his unfortunate demise? Perhaps the ship's captain should take responsibility for setting course through a storm, or the shipping company for supporting and promoting such an endeavour? Or is this a fundamental issue for the State, enacting regulation to minimise the risk of perishing in a storm at sea? The State could require that all sailors are harnessed to the ship to prevent them from falling overboard. The State could posit that seafaring be too risky a business and should be stopped altogether. Or the State could do nothing.

This inextricable link between the State and societal approaches to risk is one that has been borne out of the changing landscape of regulation throughout history. As Chapter 1 indicated, risk is a pervasive and constant feature of modern life. Risk is communicated on a constant basis, whether it be at the workplace or at home. And the communication of risk is indicative of a wider trend, as society becomes more interested (and more concerned) in how to deal with the increasing number of risks that affect our health and wellbeing. Public perception of risks has fundamentally altered in western, industrialised nations, as it is claimed that risk has displaced poverty as an overriding concern for many citizens (Beck 1992). Notions of risk have become so important that "In many respects risk has become a new lens through which

to view the world” (Hutter 2005). Democratic governments reacting to such public perceptions have put risk at the centre of their agenda. Indeed, it has been argued that there has been a move from the governance of risk to governance *by* risk (Rothstein, Irving et al. 2006).

Risk-based approaches are increasingly being implemented across various governance structures. Within the UK, several reports have indicated the importance of risk-based approaches (e.g. Cabinet Office 2002, Hampton 2005). The EU has also sanctioned such approaches as key to the application of its Better Regulation Agenda (Lofstedt 2004, Lofstedt 2007, European Commission 2009, European Commission 2010). Within the USA, risk-based approaches have formed a cornerstone of government action and these approaches have been championed by transnational organisations (e.g. OECD 2010) and international agreements, such as the Sanitary and Phytosanitary Agreement (SPS) (WTO 1995, Majone 2012).

However, risk-based regulation is more than just a mechanism for dealing with societal risks; it offers a formal set of guidelines and framework for both regulators and those being regulated. As Rothstein and Downer (2012) explain:

The concept of ‘risk’ being advocated here far exceeds the word’s long association with harms to the environment and health and safety. Rather, it offers a formal language for framing a diverse set of potential adverse consequences from policy interventions; be it to individuals, organisations, the environment or even government itself.

This chapter will trace the rise of risk-based regulation across a diverse set of policy domains and investigate the societal and institutional drivers and constraints of such an approach. As this thesis deals with regulatory regimes that implement risk-based regulation, a regime approach will be utilised. As such, this chapter will start with an investigation into the taxonomy of risk, before explaining regulatory regimes and regime function. Subsequently, the chapter will provide the historical context to the rise of risk in society and will then investigate the drivers and constraints behind risk-based regulation.

2.1 The taxonomy of risk

Even though risk-based approaches are becoming commonplace across many policy domains, there has been relatively little said about the definition of “risk-based” – specifically, the development of a common understanding of what it means to have a process or approach based upon risk. Some authors appear to accept that the epistemological debate concerning the definition has already been settled, instead choosing to focus on its application. For example, Adam M. Finkel, in introducing the volume, *Worst Things First? The Debate over Risk-Based National Environmental Priorities*, does not give any consideration to taxonomic uncertainties of “risk-based”. On the other hand, studies looking at the implementation of risk-based governance, such as Hutter and Amodu (2008) and Black and Baldwin (2010), indicate a great range of divergent implementations and contested definitions, each claiming to be the standard bearer of what is expected to be a risk-based approach (Hutter and Amodu 2008, Black and Baldwin 2010). The proliferation of risk terminology has even led on occasion to the use of different meanings within the same institution (Black and Baldwin 2011; Rothstein and Downer 2012).

As more regulators turn to risk-based approaches, this author argues that there is a clear need to investigate why, and the extent to which, such contested definitions exist. Furthermore, it is important to understand the issues that surround such an approach, as well as to appreciate why risk-based regulation has been viewed as the answer to modern regulation. Finally, it is essential to know whether risk-based regulation marks a paradigmatic shift in regulatory approaches, or is a smaller piece in the regulatory jigsaw.

2.2 Risk vs hazard

Before investigating what it means to implement risk-based governance, it is important to understand what exactly is meant by the term “risk”. Studies have shown that in institutions where risk is explicitly managed, interpretations of the term can vary wildly (Pablo 1999). In many cases, the terms “hazard” and “risk” end up being used fairly interchangeably. However, there is an important distinction between the two. “Hazard”, as defined by the Royal Society (1992) is “a situation that in particular circumstances could lead to harm”. It is important to note that there is no statement of the probability of harm being caused. “Risk”, on the other hand, is the likelihood of such a hazard occurring and the effect it would have

(Royal Society Study Group 1992, Health & Safety Executive 2012). As the Occupational Safety and Health Administration services states, risk is the “product of the probability of a hazard resulting in an adverse event, times the severity of the event” (Schollmeyer et al. 2013). Therefore, for a risk to be measured it must include the presence of a hazard, its likelihood, and the severity of its impact.

With regard to governance, risk can be further categorised into societal risks and institutional risks as defined by Rothstein et al. (2006). Societal risks are defined as both traditional and novel risks to members of society and their environment. Institutional risks are risks to the (state or non-state) organisations that regulate societal risks, and risks to their legitimacy and associated rules and methods. It can be argued that increased implementation of risk-based regulation has come about as a consequence of the colonisation of risk through increased saliency of societal risks and the institutional risks faced by organisations tasked with dealing with societal risks. This chapter will seek to explain the increased salience of societal risks, as well as the qualitative shift towards the management of institutional risks and the implications this has for the application of risk-based regulation.

2.3 Risk and Regulatory Regime Function

This PhD focuses on the regulatory regimes that deal with food safety risks. Hood, Rothstein and Baldwin (Hood et al. 2001), determine a regime to “denote the complex of institutional geography, rules, practice, and animating ideas that are associated with the regulation of a particular risk or hazard”. Regimes in this context involve a diaspora of factors that can directly and indirectly shape how regulators come to deal with both hazards and risks. These factors could include technical determinants in characterising a hazard or risk, or the institutional and normative functions of setting and enforcing regulations. Hood, Rothstein and Baldwin’s model of a regulatory regime (see fig. 1) also indicates that a risk-based approach can occur across part, or all, of regulatory action. Namely, different regulatory approaches could be split across information gathering, standards setting and enforcement. By investigating these key components of an individual regime, in this case food safety, the regulatory pathway can be comprehensively assessed.

Information gathering – The collection of information about risks. This is achieved through a myriad of different ways such as regulators conducting their own research, imposing legal requirements for reports and research from organisations, and/or voluntary provision of information by individuals and organisations.

Standard-setting – The setting of standards, goals, targets and guidelines. Standards can be set in a multitude of different ways, from applying measures from other domains or from existing technocratic expertise, to achieving standards as a compromise between two or more rival stakeholder groups. Standards can even be based upon numbers or guidelines drawn out of thin air.

Behaviour-modification – The process of changing individual or organisational behaviour, to help mitigate risks through measures of compliance or deterrence. This component can be highly problematic depending on the organisational culture it applies to. Certain groups may accept rules laid down by regulators whilst others may flaunt them if regulations aren't backed up sufficiently by detection and sanctions (opportunistic culture) or may even be drawn to products that have been deemed to be dangerous (defiance culture).

Figure 1. Core components of regulatory regimes (Hood, Rothstein and Baldwin 2004)

The ways in which regulatory regimes can be affected vary from the wider political and social contexts of regulatory action, down to normative differences in the way different institutions might seek to regulate. With regard to the wider context, the way in which institutions perceive and react to hazards and risks (through constitutional arrangements, public perception etc.) will have an important bearing on the regulatory regimes employed to deal with such problems. For example, if an important stakeholder (e.g. an affected community) has a substantially risk-averse outlook to a set of hazards, it could be assumed to have a low tolerance of risks and expect regulators to produce and enforce strict regulations to try and lower the amount of risk that the community is exposed to. Conversely, if a government feels that business and industry is hampered by too many rules and regulations, there would be a political will to cut regulation and increasingly allow market forces to deal with risks in the hope of boosting growth.

At first glance, the formulation of a basic assumption of what it means to be risk-based might not seem problematic. Essentially, risk-based approaches are founded upon a rational and objective system that reduces risks based upon their impact (Dahle, Dybvig et al. 2012). This is not a particularly precarious starting point. A rather distilled manifestation of this rule is that a fire department may prioritise dealing with a hospital that is burning down as opposed

to a secluded garden shed, based on the supposition that a hospital on fire will present a greater impact (in the greater number of people exposed to fire) than the shed.

However, clearly identifying risk-based approaches across regulatory regimes can prove challenging, even if a regulatory regime overtly states that it is risk-based. This is due to the diversity in the application and interpretation of risk-based regulation within both the same, and different, policy domains (Rothstein, Irving et al. 2006). Risk-based regulation does not lend itself to one clearly definable entity. As Bostock and Hutter (Lloyd-Bostock & Hutter 2008) contend, “Risk-based regulation is best conceived of as a cluster of tools and characteristics rather than a clearly defined and coherent method”. And as Klinke and Renn admit, “Past experiences demonstrate that there is no simple recipe for evaluating and managing risks” (Klinke and Renn 2002). However, risk-based approaches do appear to have a common theme running through them. Black and Baldwin (2010) lay out five core threads that run through these approaches and these can be linked to the regime approach, as indicated in fig. 2.

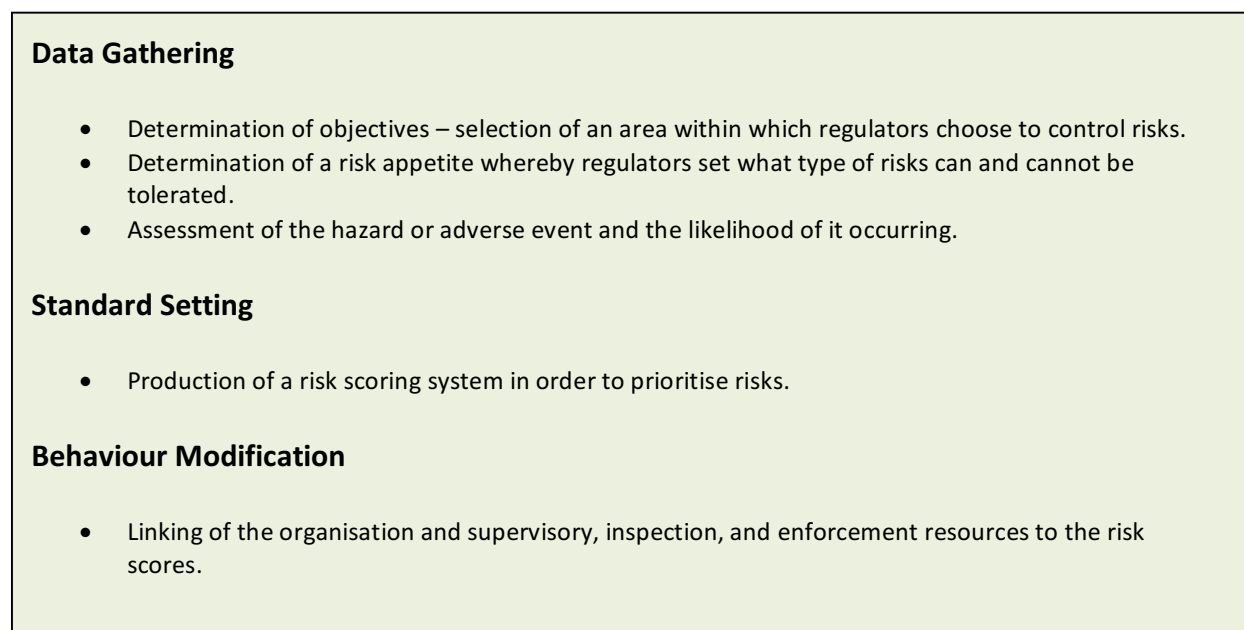


Figure 2. Core components of risk-based regimes (Black and Baldwin 2010)

However, Black’s (2005) definition of risk-based regulation goes beyond more than just a “cluster of tools”, explaining how institutional pressures have shaped its definition:

It has two distinct meanings, which are often conflated. The first refers to the regulation of risks to society: risks to health, safety, the environment, or less usually, financial well-being... The second, emergent meaning of risk-based regulation refers to regulatory or institutional risk: risks to the agency itself that it will not achieve its objectives. In this newer sense, risk-based regulation involves the development of decision-making frameworks and procedures to prioritise regulatory activities and the deployment of resources, principally inspection and enforcement activities, organised around an assessment of the risks that regulated firms pose to the regulator's objectives. (Black 2005)

Risk-based systems therefore allow regulators to target the application of resources. Instead of attempting to implement and enforce a large set of rules within a certain policy domain, risk-based approaches prioritise action through the scoring and rating of risks. With limited resources, regulators can set their risk appetite so that higher rated risks receive more regulatory action than lower rated ones. However, it is important to note that risk-based regulation doesn't just seek to manage and rank the risks faced by regulators. It also seeks to reveal the operating risks, or business risks, that regulators must deal with when regulating impacts. These are essentially the risks faced by the regulating organisations themselves. For example, the legitimacy of a regulator can be called into question due to a myriad of operational failings such as enforcement failures or liability issues (Rothstein and Downer 2012).

With respect to the makeup of regulatory regimes, risk-based approaches can be used along the key components of the regulatory pathway. Risk tools such as horizon scanning and risk assessments can be used in the information gathering stage to help identify regulatory goals. Risk management can be utilised for key parts of the standard setting stage, deciding upon the regulator's risk appetite and targeting and setting the remit for regulatory action against specific hazards, providing a blueprint for how regulatory resources should be allocated. Effective and coherent risk communication at the behaviour-modification stage can also ensure that individuals and organisations understand and interpret a regulator's message. Indeed, monitoring a hazard can also be based upon tools of risk analysis so that regulators can react to the change in a system they seek to regulate.

Risk-based approaches aren't simply about identifying and acting upon clearly defined probabilities and impacts. As Black and Baldwin make clear, risk governance brings a range of factors into play, including “the simplicity or complexity of the causal chain between hazard and harm; the degree to which probability and/or impact are known or uncertain; the nature and distribution of the impacts (remediable or irreducible, concentrated or diffused); and the socio-political contestability of the risk” (Black and Baldwin 2011). Factors like these show that risk-based regulation isn't as straightforward and clearly delineated a mode of governance as some hope or claim it to be.

The next section will provide an historical context, explaining the prominent rise of risk in society and the associated reliance on the governance of societal risks, as well as the implementation of the governance *by* risk as a means of “good governance”, due to drivers and constraints inherent in the reflexive combination of societal and institutional risks.

2.4 The Rise of Risk in Society

Almost in parallel to the ways in which society views risk, there are advances in the utilisation of the probabilistic tools of risk. The scientific revolution of the 18th century brought into question scholastic teaching and the ancient worldviews on which it was based, as natural philosophers embarked on an increasingly ambitious set of scientific and philosophical enquiries (Broad 1959). Central to this was the increased employment of probabilistic statistical tools in research and across widening areas of governance. Commerce also employed probabilistic techniques to remain on top of the exponential increase in international trade, providing Lloyds of London with the means to underwrite international trade (Bernstein 2012). This trend continued unabated into the 19th century with statistical laws forming the cornerstone of government and commercial action (Hacking 1990). Thus, the probabilistic tools of risk were becoming increasingly relevant to modern society.

We have always faced risks of different kinds. However, the nature of the risks that societies have faced, and the way in which risks have been perceived have fundamentally changed over time. The effect of these changes with regard to how society has decided to deal with risks, is profound. Sociologists have identified three core narratives that seek to explain these important changes and their implications (Mythen 2008). The first is Ulrich Beck's greatly

debated work, *The Risk Society*, the second is Michel Foucault's concept of governmentality, and the third is Mary Douglas' cultural theory of risk.

The first causal explanation centres on Beck's assertion that western, industrialised society has replaced poverty with risk as its central imperative. As poverty has become less of a central driver for societal action, risk has stepped in to fill the vacuum. This change has been brought about through the progression of society from pre-industrial, through industrial (modernity) and finally to the current risk society (postmodernity). Beck argues that risks in pre-industrial societies tended to be the product of natural hazards, were often localised and could be mitigated by individuals (with sufficient access to resources and social standing) and by tried and tested institutional responses. A simplified example here is flooding – those affluent in society could afford to live on an elevated plain, which would not be affected by such a hazard, while governmental institutions could deny building on flood plains. Industrial societies, underpinned by great advances in science and technology, complemented these natural hazards with anthropogenic ones, which are characterised as diffuse and difficult for institutions to mitigate. Here, an example often used is nuclear fallout from a reactor meltdown. Such a fallout does not observe strict boundaries, so could affect wide-ranging areas. This in turn makes it very difficult for government institutions to assess potential impact and spreads its distribution more evenly across social hierarchies. In Japan, the Fukushima nuclear reactor meltdown in 2011 exposed such limitations as different national governments, having assessed the risk, and with a 20km evacuation zone in place, gave conflicting advice as to whether it was safe for their nationals to remain in the capital Tokyo, more than 200km away.

It is this change in social imperative, from poverty to risk, coupled with an increasing failure to technically assess and manage risk, that leads to the risk society. Where the green shoots of modernity signalled the development of transformative technologies (such as nuclear power), postmodernity delivers a contrasting and dystopian account. Citizens begin to distrust both governments and experts' ability to highlight and control emerging risks from new technologies. Indeed, with rapid advancements in science and technology, experts lack the tools to be able to control these risks. According to Beck, governments of industrial societies try to alleviate their citizen's heightened risk perceptions by "exporting" risks to countries that require the subsequent inlay of capital in order to deal with poverty. As the Brazilian planning minister announced in 1972, "Brazil can still afford to import pollution" (Beck

1992). The 1984 Bhopal incident in India and the 1984 oil spill fire in Brazil can be interpreted as a consequence of developing countries accepting risks that industrialised countries shun. However, as discussed, the far-reaching effects of anthropogenic risks means that the risk can still return.

Another expansive narrative centres on anthropological theories based upon the changing ways we have interpreted risk and the notions of blame that are inextricably attached to risk. Mary Douglas studied how different social groups perceived and dealt with risk and attributed differences to a person's social standing (grid) and the amount of cohesion within a society (group). By ascribing four typologies, Douglas sought to explain how cultural bias affected different groups' risk perceptions. Douglas' work also closely linked risk with blame, looking at how indigenous cultures used "others" as a means of absolving themselves of blame and ensuring the dominance of their culture and practices. Douglas (2002) argued that before the scientific and industrial revolutions, risks were a product of God's wrath, vengeful spirits or superstitions held by the general populace, rather than the actions of man or the forces of nature. Douglas argued that the notion of sin could be used as a construct for the ruling classes to pass on and even apportion blame. Risks befell people not because of factors such as insanitary living conditions, communicable diseases or simply being in the wrong place at the wrong time, but because of a lack of Christian virtue. "Before Christianity, the Bible is full of such interpretations: the defeats of the Israelites by foreign armies, destruction by earthquake, plague, and drought, were attributed to God's anger for sins" (Douglas 2002). The concept of blame was therefore reasonably reflexive – the victim often culpable for not having suitably atoned for a previous sin. The idea that the victims were accountable for what befell them was actually enforced by societal pressures and hierarchies. The Great Plague of London, the last epidemic in England linked to the bubonic plague, which during the 14th century alone had killed approximately 200 million people in Europe and Asia, reinforced class boundaries:

The danger of contagion was employed to justify the new social politics of the sixteenth century municipalities... the isolation procedures taken against the plague would not have been so savage if the poor had not presented a conspicuous target which was to attack for other reasons (Slack 1988)

As Douglas noted, “the English well-to-do saw the incidence of plague as the sign of God's judgement directed against the sins of the poor” (Douglas 2002). With the coming industrialisation of society in the 18th and 19th centuries and the greater freedom of movement and opening of communities, religious scepticism was on the rise and the language of risk was altered (Bernstein 2012). Risks were increasingly viewed less as a by-product of God's action on Earth, and more as a result of the actions of man. Giddens (Giddens 1991; Giddens 1999) argued that the weakening strength of the church, coupled with advances in scientific thought, led to the creation of new knowledge and institutions (such as the media) that put risk increasingly at the forefront of people's minds. Notions of blame had now shifted from superstitious happenings and religious edicts to the creators (and the regulators) of anthropogenic risks that form the cornerstone of Beck's risk society concept. From a risk society perspective, Douglas' “others” have become the governmental institutions and expert bodies, trusted less and less by citizens concerned by the myriad of risks that are continuously identified.

Although the risk society narrative presents governments and experts as increasingly mistrusted by their citizens due to their failure to deal with the plethora of man-made risks, Michel Foucault's governmentality theory strikes a decidedly different tone. Central to this theory is the use of discourse, broadly defined by Mythen (2008) as “sets of ideas, beliefs and practices that present ways of representing knowledge”. Far from authorities shirking from dealing with risk, they use risk as a foundation for discourse that serves to exert influence over behaviours and practices.

However, there are also more specific actor-driven explanations for the rise of risk in society. Public opinion, public interest groups and industry can be accredited with putting risk at the forefront of society and the subsequent increase in regulation of risk.

From a public opinion perspective, public reaction to accidents can lead to increased regulation of risk. This effect can be prominent after major accidents or disasters and the subsequent “tombstoning” regulation that is created is a regulatory response to public outrage. Public outrage has led to the specific establishment of new regulators, such as the (now defunct) UK Adventure Activities Licensing Authority (AALA) following the death of four teenagers in a canoeing accident in 1993, or the reorganisation of regulators, such as the break-up of the Ministry of Agriculture, Food and Farming in the aftermath of the BSE crisis

(see Flynn et al. 2003). Public interest groups can also be an important driver, providing a focused platform for change in regulatory action. The emergence of new social movements in the USA in and around the 1970s in response to environmental injustices and the publishing of influential publications such as Rachel Carson's *Silent Spring* (see Murphy, P.C. 2007) led to the creation of many such groups. The creation of the American superfund in response to the Love Canal incident (see Colten & Skinner 1996) can be seen as testament to the political influence of public interest groups. Finally, industry may push for the regulation of risk as it can portray itself as socially responsible in dealing with the larger risks to society (Stigler 1971). At the same time, "trading up" (Vogel 1997) can occur as larger industries gain a better foothold in the market, complying with more stringent regulations that smaller competitors can't afford, or lack the expertise, to comply with.

The increased saliency of risk at a societal level therefore brought with it a greater desire to confront such risks. Such need for action was complemented (and in part instigated) by a change in governance structures that increasingly put the framing of regulatory problems as risks at the forefront of "good governance". This theory of "risk colonisation" posits that by framing regulatory problems as risks, increased control of said risks increases its salience (Rothstein et al. 2006). This is in stark contrast to Beck, who suggests that increased salience of risk is due to a lack of control (Beck 1992).

However, an increased emphasis on the governance of risk does not necessarily equate to governance *by* risk. In order to fully assess the implementation of risk-based regulation, it is necessary to investigate the institutional drivers and constraints that shape risk-based approaches to societal risks. The following section will investigate the regulatory context in which risk-based regulation is applied and the societal and institutional factors that drive and constrain its application.

2.5 From Regulation of Risk to Regulation by Risk

At the same time as the tools of risk analysis were being promoted, fundamental changes to governance structures were changing, and continue to do so. Risk increasingly appears to form the foundation of "good" governance, indicating through evidence-based inquiry the remits of regulation and demarcating the limits of governance. It allows regulators to state clearly what falls within the realms of regulation and what does not (whether that be for cost-

benefit, risk-risk considerations, scientific certainty etc.). Accompanying the apparent increase of the term “risk” in governance, we find the implementation of “risk-based” approaches (risk-based regulation). However, even though risk-based approaches are now increasingly applied across a more diverse range of policy domains, application is in no way consistent across different domains and even between regulatory institutions within the same domain.

Regulatory agencies are constrained by a significant number of institutional factors. For example, Rothstein et al. (2006) provide a list of potential constraints, “regulatory decision-making and implementation are characterized *inter alia* by constrained resources, competing priorities, cognitive uncertainties, bounded rationalities, conflicting interests, ungovernable actors, and unintended consequences”. These institutional risks can undermine the effectiveness of regulatory action and even the validity of the regulatory organisation itself. Risk-based regulation is an original regulatory approach as it not only accounts for societal risks, but also manages the institutional risks affecting regulatory agencies.

Risk-based approaches are not new; regulators have been using probabilistic calculations of risk to inform standard setting and enforcement for some time. Examples include the health and safety regime in the UK, based upon a “tolerability of risk” guidance first published in 1988 (HSE 1992), whereas in the US, Cost Benefit Analysis (CBA) has been a cornerstone of regulatory action since the Nixon administration. As mentioned in the previous section, the probabilistic determination of risks was present in the insurance industry of 18th century England. However, the implementation of risk-based regulation as a central dynamic of regulatory action can be connected to the rise of neo-liberalism after the Second World War. The neo-liberal approach was critical of the pre-war years, marked by inefficient government action with expensive and heavy-handed regulation which stifled economic growth by weighing down business and innovation (see Hayek 2012). This contrasted with the Keynesian welfare state, which advocated the proactive intervention of the state in order to prevent economic malaise. Keynes himself was highly critical of the probabilistic role of statistics, citing that probabilistic determination ignores the fundamental uncertainty of economic action (Bernstein 2012).

A neo-liberal doctrine, however, sought to draw back state intervention and rely on the internal balance of market forces. Regulators were not only performing in an inefficient way,

they were also restricting business with a plethora of regulations that were hampering growth. However, as a first attempt at creating more effective regulatory action, Progressive Public Administration (PPA) sought to separate institutional organisation of the public sector from that of the private sector, in order to guarantee that the public sector produced a class of regulators who were not tempted by the high risk/high reward nature of their private counterparts (Hood 1995). Also, central to PPA was a reliance on implementing an exhaustive process of checks within regulators to ensure distance between regulator and regulated, avoiding favouritism and corruption (Hood 1995).

But in the face of an increasingly prominent neo-liberal perspective, PPA was to all intents and purposes disposed of in favour of a regulatory dynamic that would seek to bring government and industry closer together, rather than keep them apart. “New Public Management” (NPM) in many ways reversed the key pillars on which PPA was based upon. The private sector had turned from being the embodiment of corruption and indulgence to the benchmark by which regulators were now set. Efficiency drives demanded that regulators remain competitive and were able to legitimise their work (Hutter 2005). Regulators had to exhibit strict discipline in relation to utilising their resources (Hood 1995). Auditing became a necessity as a system of checks and balances became the *de facto* norm, leading to Power’s assertion of an “audit society” (Power 1997). Just as pivotal, regulators had to show due care not to impede business with a complex structure of procedural rules and regulations (Hutter 2005). The overarching dynamic here was that government should not get in the way of commerce and industry, allowing market forces to dictate and businesses to grow. This dynamic was clearly evident throughout the 1980s and 1990s within many governments. For example, in the UK, deregulation had become the guiding policy of British administrations, “During the mid 1980s Britain witnessed waves of deregulatory initiatives concerned with the costs of compliance, the over-regulation of business and institutional reforms to control this” (Hutter 2005). A similar focus on cost benefit was evident within both Europe (Majone 1990) and the USA (Breyer, Stewart et al. 1999) during a similar period.

The post-war years have also been defined by the rise of the “regulatory state”. Due to the perceived high economic cost of the welfare state, the regulatory state sought to transfer a significant portion of the cost of regulation onto the regulated entity, with specialist government agencies tasked with overseeing self-regulation practices (Majone 1997). Government action was therefore fundamentally changing from a provider within a welfare

state to a regulator in the regulatory state. However, with the rising saliency of societal risks and the non-majoritarian status of many regulatory agencies, there has been greater pressure to indicate validity of regulatory action through increased accountability and transparency. Power's "audit society", whereby "waste watchers, quality police and sleaze-busters" (Hood et al. 1999) are inspecting public-sector organisations, coupled with new means of investigating regulatory action (e.g. through internet searches, freedom of information etc.), ensure that regulators face increasingly high institutional risks. Rothstein et al. (2006) argue that the increased saliency of risk ensures that regulation is subject to its own regulation – if there wasn't an increased need for transparency and accountability, institutional risks for regulators would be lower.

2.6 Drivers of Risk-based Regulation

Risk-based regulation helps reinforce organisational validity in the face of requirements for increased accountability and transparency. Risk-based regulation falls in line with Power's "audit society" as it exhibits an organised approach to managing problems through clearly indicating a risk governance approach to management (risk assessment, risk management, risk communication). Risk-based approaches clearly reveal which dangers are being managed and who is managing them. Clarke illustrates that even when there are dangers that are impossible to manage (e.g. no historical incidence from which to learn from, lack of regulatory resources), regulators still implement fantasy documents, in order to satisfy transparency and accountability demands (Clarke 1999). Indeed, a risk-based approach can be seen as a strategy of "protocolisation", using economic and numeric rationales to cement organisational validity, "risk assessment can be seen as a way of formalizing organizational operations in order to provide bureaucratically rational 'due diligence' defences in the face of increased accountability pressures" (Rothstein et al. 2006).

Risk serves as a means to legitimise regulation through not only showing to what extent something should be regulated, but also in giving justification and legitimacy to the extent that regulators enforce. Risk-based regulation therefore accounts for failure and stipulates that failure is a plausible outcome of risk-based approaches. Risk-based approaches only offer probabilities, not certainty (Rothstein et al. 2006). As a result, risk-based regulation becomes a useful blame deflection tool, offering justification for when something goes wrong (Rothstein et al. 201). Related to regulatory remit within risk-based regulation is the notion of

“acceptable risk” (Fischhoff, Slovic et al. 1977, Heyvaert 2011, Rothstein and Downer 2012), which essentially indicates that a smaller risk doesn’t require the resources or the attention that a larger risk does.

Furthermore, risk-based approaches tend to be more nuanced than standard regulatory action, as they provide a range of different options for compliance and enforcement. As Rothstein and Downer explain, “Modern, risk-based regulatory regimes are typically characterised by the use of a broad suite of tools encompassing voluntary agreements, trading schemes, environmental management systems and taxes in place of, or in concert with, the traditional regulatory model (authorise, check, enforce)” (Rothstein and Downer 2012). As such, risk-based regulation tends to be seen as more malleable and responsive than the more conservative “command and control” approaches, where regulation “is pragmatic and replaces the choice between compliance or deterrence approaches with a highly flexible, situationally specific, and adaptable approach” (Dahle, Dybvig et al. 2012).

What also makes risk-based regulation different from previous forms of regulation is that a decision-maker’s first port of call is identifying and evaluating risks within his/her domain, rather than simply enforcing an unmanageable list of rules. As Black and Baldwin explain, “Risk-based frameworks require regulators to begin by identifying the risks they are seeking to manage, not the rules they have to enforce” (Black and Baldwin 2010). Therefore, risk-based regulation tends to be highly outcome-focused. Indeed, the need to apply a robust and explicit framework for dealing with risks is seen as a requirement for a risk-based approach (Adil 2008):

The main difference between those who claim to be risk-based and those who do not, is the extent to which they attempt to apply an explicit, consistent, strategic and operational framework to these decisions, and the level of proactive work (intelligence gathering and its appropriate interpretation) undertaken to deal with emergent risks and prevent harm occurring before the event.

Hutter argues that risk-based approaches become more salient as governments become less direct and less visible (Hutter 2005). “Catch all” methods of regulation are being replaced with more target-orientated modes of action through risk-based approaches. It is this target-

orientated approach that provides a solution to neo-liberal accusations of regulatory creep within governance.

A targeted and economically rational approach not only combats regulatory inefficiency, but through numeric evidence-based rationalisation it also provides a legally defensible position. Risk-based regulation offers legitimate rationalisation for non-majoritarian regulatory agencies (Rothstein et al. 2006). This legitimacy is clearly seen in the implementation of quantitative risk assessment in the USA following the Supreme Court's ruling on the benzene standard. In 1980, the OSHA had appealed against the Fifth Circuit Court of Appeals ruling against OSHA's regulation stating that occupational exposure to benzene (a carcinogen) should be reduced from 10 ppm (parts per million) to the least-feasible-risk of 1 ppm (Thomas 1982). However, what came out of the Supreme Court's ruling, in *Industrial Union Department (AFL-CIO) v. American Petroleum Institute*, was the need to show significant risk, rather than demand the lowest feasible risk. This was enshrined in the reliance on quantitative risk assessment as a means to calculate such significant risk (Callahan and Sexton 2007). As Majone described, "The Supreme Court not only confirmed the legitimacy of quantitative risk assessment; it effectively made reliance on the methodology obligatory for all American agencies engaged in risk regulation" (Majone 2012).

Since the benzene case, the USA has been a major proponent of regulatory impact assessment. This is clearly evident in *Risk Assessment in the Federal Government: Managing the Process* (NRC 1983), commonly known as the "Red Book" and the blueprint for the application of risk assessment by federal agencies. Furthermore, the US government set up the Office of Information and Regulatory Affairs (OIRA) to ensure that all new regulation that is implemented is subject to regulatory impact analysis (Morrall 1992, Graham 2008, Shapiro 2010). The impact of every regulation is assessed from the perspective of cost-benefit and risk-risk trade-offs. In principle, it is therefore argued that only significant risks are regulated – those whose cost lead to greater benefit and whose regulation does not lead to the emergence of alternative, greater risks.

The extent to which risk forms a part of governance differs between the US and EU. Within the USA, cost-benefit and risk-risk analyses take precedent when enacting regulation that is targeted at "significant risk". With regard to the EU, some commentators have argued that its

approach has been more inclined to regulating towards the lowest-feasible-risk end of the spectrum rather than focusing on significant risk (Majone 2012).

However, the EU's subsequent introduction of the Better Regulation Agenda has swung the regulatory pendulum back towards a more risk-based approach (Lofstedt 2004, Lofstedt 2007). This is because the Better Regulation Agenda advocates the reduction of regulatory burdens on business and the need for a more streamlined and targeted approach to risk. This is achieved through increased implementation of regulatory impact analysis, assessing various risk trade-offs in the implementation of regulation. The EU has set up the Impact Assessment Board (IAB) (Meuwese 2008), which is similar in essence to the USA's OIRA. However, it does not have the institutional strength that OIRA exhibits, as it only operates in an advisory role and cannot "send back" regulations in the same way that OIRA can.

Finally, the institutional risks associated with risk-based regulation can sensitize regulators to look at societal risks in different ways, potentially leading to better management of societal risks, as regulatory action isn't fixed by bounded rationalities to quite the same extent. This can lead to numerous benefits such as "more research, greater professionalization, more robust evidence-based decision-making and associated regulation" (Rothstein et al. 2006). New societal risks can also lead to new institutional risks and therefore risk-based regulation can induce a feedback loop of risks.

As mentioned, risk-based approaches are being increasingly implemented across a diverse range of policy domains. This has led to the "risk management of everything" (Power 2004) and the prominence of what Black terms the "New Public Risk Management" (NPRM) (Black 2005). NPRM builds upon the crosscutting of internal regulation that was exhibited between government and industry in the case of New Public Management (NPM). On the one hand NPRM is the "self-challenging" element of an organisation (Power 2004) that defines risk as the failure of a department to meet its objective (government), or the risk to profitability (industry). It is the implementation of an internal risk management structure to account for failure from either internal or external risks (Black 2005). The second important facet of NPRM is that it sets out how risk-based approaches are implemented and the way in which societal and institutional pressures affect these approaches. It is this second strand that forms the primary focus of this PhD; this strand challenges the assumption that risk-based approaches are equal and uniform.

Risk-based regulation therefore claims to offer a robust, targeted and scientific framework for prioritising risks and directing regulatory action. Furthermore, it allows for an intelligent allocation of resources at a time when regulatory budgets are being stretched and new risks are constantly being identified. However, risk-based approaches are not the panacea of risk regulation, and are afflicted by several key problems.

2.7 Constraints on Risk-based Regulation

As previously discussed, risk-based regulation is not applied in a universal manner and its diverse modes of implementation reveal it not to be the robust and straightforward regulatory framework that many governments and industry claim it is (MacGillivray, Alcock et al. 2011). There are also issues regarding whether risk-based regulation is the fix to the regulatory problems that proponents of this approach argue it to be.

Risk-based regulation is not seen simply as a straightforward antidote to the larger problems of regulation. As previously stated, it appears to be less about an all-encompassing philosophy and more about a collection of tools and characteristics. Indeed, part of the attraction of stating that they utilise risk-based approaches is that regulators can apply a rather vague label to a range of regulatory actions in order to guarantee procedural validity.

Risk-based regulation does not resolve a variety of problems associated with regulation. Indeed, a regimented risk-based approach can highlight the procedural challenges that lie ahead for regulators. Black and Baldwin (2010) argue that even though risk-based systems are suited to providing a relatively clear means of defining which risks are tolerated during the information gathering phase (through the implementation of risk scoring systems and the subsequent prioritising of risks), risk-based approaches do not provide a mechanism for what should happen in response to the identification of a high prioritised risk. The criticism here is that risk-based approaches can only purport to solve some of the issues surrounding regulation. In order to move through all the stages outlined in the regime framework, risk-based approaches need to be supplemented with other philosophies of regulation. A risk-based approach may highlight that a company is producing a chemical that registers high on a risk scoring system. However, such an approach cannot indicate whether the company's compliance should be increased through punitive measures (such as a fine) or a softer

approach (such as providing educational material). Indeed, one of the major appeals of risk-based regulation – that by prioritising risks there is less reliance on rule-making – can be challenged. For example, if a regulator has found an intolerable risk and wishes to enforce punitive damages on a company responsible for that risk, rules must be in place to allow that enforcement action to legally take place. Risk-based approaches do not do away with rule making and in many ways are dependent upon the relevant rules to be in place, in order to be effective.

The institutional risks faced by regulators can also divert resources intended to go into the management of societal risks, “For example, as regulatory frameworks have become established, accumulating case law, legal duties, and spending targets have placed duties on regulators that can conflict with the management of societal risks” (Rothstein et al. 2006). Institutional risks can deflect organisations away from their core business and leave regulators fighting a vicious circle of validity rather than actually dealing with the societal risks they were tasked to deal with.

With regard to the objective approach to regulation that risk-based regulation endorses, under conditions of high scientific certainty, risk-based systems allow for an evidence-based assessment of the risk posed. However, the risk ranking required can be quite subjective in nature. How to determine the cut-off point between a tolerable and intolerable risk is in many ways down to the organisational culture of the regulator tasked with drawing the line. Organisational culture can dictate how good a specific regulator is at making the distinction between a tolerable and intolerable risk, and how well the risk-based system produced operates under stress during a crisis.

Risk-based regulation has been put forward as a highly robust and objective approach to regulation. Through the application of intelligence-based scientific risk assessment, regulators should end up with highly objective results they are able to apply. However, no matter how objective the science provided has been, there is still a need to make highly political and possibly contentious decisions based upon the information. The outcome of risk-based regulation will still be subjective in nature, even though the intervening process may have been objective. Such a fear of mixing the objective nature of scientific risk assessment with the subjective nature of risk management has previously led to government institutions keeping the two parts of risks analysis separate (NRC 2009).

The objective stance of regulators themselves can be further investigated by looking at capture theory and business risks. Capture theory states that regulators aren't acting in the best interests of the public they serve, but instead are captured by specific stakeholders with specific interests (Stigler 1971, Chittenden, Ambler et al. 2007). This theory has been shown to be not entirely accurate. MacGillivray et al. argue that such claims of regulatory capture skew debate further from reasoned and objective discussion over the "considerations of science, values, and economics" (MacGillivray, Alcock et al. 2011). However, the effect of entrainment has shown that the objective basis to risk analysis can be ignored or tweaked. The theory of entrainment essentially denotes that a risk can be caught up in a broader political discourse where the end regulation is conducted as per the pre-existing regulatory approaches associated with the political issue rather than specifically to the risk at hand (MacGillivray, Alcock et al. 2011).

It must also be noted from the discipline of psychology that decision-making is inherently a subjective endeavour. Tversky and Kahneman's work into heuristics and biases shows that, especially under uncertainty, we are just as likely to apply "rules of thumb" judgements as we are to try and act in a purely objective manner (Tversky and Kahneman 1974). Risks are subjectively perceived and acted upon.

The perception of risk brings us to issues surrounding the *public* perception of risk, and the effect this may have on a risk-based approach. If we return to the previous discussion on "acceptable risk", how is "acceptable" defined? (Hutter 2005) Within a risk-based approach there are frameworks to scientifically guide the regulator, through which risks are deemed less acceptable and therefore require more attention. However, the public may have a different perspective on what appears acceptable. The social amplification of risk literature highlights many instances where public and stakeholder perceptions of risk do not align with science-based reasoning achieved through risk-based approaches (Kasperson, Renn et al. 1988, Pidgeon, Kasperson et al. 2003). Essentially, in the event of a risk impacting, it is very hard for a regulator to explain to those affected that the risk will continue to receive minimal levels of regulation because it is deemed as being within an acceptable range (Black and Baldwin 2011). Furthermore, will the public willingly utilise low risk priority services that have had less regulatory oversight, or services that are deemed to be higher risk? For example, would a patient feel comfortable being treated in a "high-risk" hospital?

Public pressure (as seen with “tombstoning”, for example, enacting regulation in response to a crisis) can lead to the passing of regulation without first probabilistically calculating the risk. This assessment is based on the EU’s application of the precautionary principle (Pesendorfer 2012), which essentially stipulates that even within a climate of scientific uncertainty, hazards should be acted upon. This “better safe than sorry” approach claims to put safety as its paramount concern, ensuring that it isn’t a case of “too little, too late” when protecting against the potential impact of uncertain risks (Cameron and Abouchar 1991, Conko 2003, Stirling 2007). One could define this approach as hazard-based as opposed to risk-based, as hazards are regulated before there is time to calculate the risk of any impact occurring. The EU’s recent handling of Bisphenol A (BPA) in baby bottles for infants is an example of a hazard-based approach (see Löfstedt 2011).

Differing risk perceptions are not only the domain of the public. Decision-makers themselves have biases. In many ways this returns to the objective versus subjective debate. The organisational culture of the regulator itself will dictate how its regulators perceive risk. A risk scoring system may look highly objective in that it provides numerical values based upon evidence-based discourse, but regulators are still making subjective calls on how good they may consider a company is at dealing with risks and how good a company’s safety system is at dealing with large amounts of stress. Furthermore, from a philosophical point of view, there is an assertion that expert estimates of risk are social constructs of the regulators who design the systems (Adams 1995, Luhmann 2005). “The constructive camp claims that risk assessments constitute mental constructions that can be checked at best against standards of consistency, cohesion, and internal conventions of logical deduction” (Klinke and Renn 2002). This is in contrast to the realist philosophy that asserts that these risk estimates are both valid and a true observation of hazards, and therefore can be acted upon confidently. These are two extremes of the debate and a middle-ground appears to better reflect the objective base of scientific information, whilst recognising that expert knowledge is not and cannot be produced within a social vacuum. The exact concepts and methods that regulators employ within a risk-based system can lead to them producing different results and implementing different standards. This essentially leads to a Kuhnian incommensurability (see Kuhn 1996) where risk perceptions will vary between different experts looking at the same risk domain.

In addition, the intrinsic matter of business risks can force a regulator to abandon the objective approach afforded by risk assessment (Rothstein, Irving et al. 2006). If these institutional risks are perceived to be too great over a certain regulation, say that there is a groundswell of public feeling against it or the regulator is found to be liable for too much, then the regulator will be inclined to change or abandon the regulation.

The increasing influence of perception on policymaking has led to a certain amount of frustration. In the USA, Justice Stephen Breyer, who advocates risk-based approaches to regulation, has written about the “vicious circle” whereby public perception shapes legislators, legislators shape public perception, and both end up shaping regulation (Breyer 1993). As a result, Breyer argues for the depoliticizing of certain risks, so that public perception cannot unduly influence the risk-based approach: “A depoliticized regulatory process might produce better results, hence increased confidence, leading to more favourable public and Congressional reactions” (Breyer 1993). Breyer argues that risk-based regulation offers a situation to the “vicious circle” as it alleviates public pressure due to the robust and transparent evidence base that is central to risk-based approaches.

However, doesn't such “depoliticization” go against democratic values? As regulation in a democratic society is supposed to serve the interests of its citizens, surely precluding public interest in risk regulation is inherently undemocratic? Furthermore, the public understanding of science literature suggests that a contextual approach reveals underlying reasons and experiences that could potentially help in regulating a risk (Gregory and Miller 1998, Miller 2001). Indeed, even the most unfounded view offered by public perception can hold information of potential use when regulating a risk (Midgley 2000).

Another major issue with risk-based approaches is the role of uncertainty (Dakins, Toll et al. 1994). When there is certainty in the scientific information provided when analysing risks, calculating probability and impact can be relatively straightforward. However, where the scientific information is contested or there are gaps in the information provided, regulating through risk-based approaches proves difficult. Uncertainty can greatly affect the regulation produced. This is because the scientific information underpinning the regulatory approaches could be wrong, subject to change, and arguments over the science itself can lead to regulation being viewed suspiciously by legislators and the public alike. However, uncertainty is not measured on the two integers of certain and uncertain; it exists along a

continuum of different levels (Majone 2012). Therefore, risk-based calculations can still be made even within certain levels of uncertainty; the approach is not entirely hamstrung in such a climate. Indeed, a significant amount of regulation takes place within areas of uncertainty. Finally, Wynne's distinction of known unknowns (that we know we have gaps in our knowledge) and unknown unknowns (that we don't know there are gaps in our knowledge), reveals further consequences for risk-based approaches (Wynne 1992). To act in the knowledge that uncertainty exists is quite different to acting without knowing such uncertainty exists. Unknown unknowns could lead to risks being categorised at a lower level than necessary.

Issues of complexity, not only regarding a risk-based approach itself but also the risks themselves, can affect such regulation (Black 2010). Research has shown that risk-based approaches are applied in a variety of different ways. It is claimed that no two approaches are the same (Black and Baldwin 2010). This bodes well in the sense that such approaches are flexible and can be used in a diverse range of regulatory problems. However, it questions the logic of risk-based approaches providing a robust regulatory framework. This brings us back to the issue of differing ideas of risk and what it is to be "risk-based". With the terminology blurred, it is difficult to consider risk-based approaches as a distinct method of regulation.

Finally, as for the risks themselves, their complexity is not only defined by inherent levels of uncertainty but also by the changing nature of many risks. A risk is not necessarily a static phenomenon but can be prone to change. Black and Baldwin make this point when considering regulation of low risks (Black and Baldwin 2011). In order to keep changing risks in check, constant surveillance and the recalculation of risk factors are required. This is expensive and time consuming and goes against the mantra that low risks should require fewer resources. The perception of risk-based approaches as effective and less costly is somewhat dispelled. Furthermore, in order to address a changing risk, resources need to be pulled away from other risks, thereby causing secondary consequences for the risks that have been downgraded to accommodate the fluctuating risk.

2.8 An overview of studies into risk-based regulatory regimes

Existing studies into the success of risk-based regulation indicate the breadth of application that it has enjoyed across varied policy domains, from banking to flooding, health care to

education. But what these studies show is that risk is not the universal organizing concept that it is trumpeted to be (Rothstein et al. 2013). Rothstein et al show that risk-based regulation does not only differ in application inter and intra policy domains but also across different countries. Preliminary investigation into risk-based regimes by other authors appears to corroborate this view.

Black (Black 2004) compared risk-based regulation in financial services in Canada, Australia and the UK. The core motivations for adopting risk-based regulation were similar across all three countries, each expecting risk-based regulation to provide efficient regulation that instigated effective allocation of limited resources available and set out the remit of regulatory action and risk management of failures. However, there were clear differences across each country when it came to the enforcement of risk-based regulation. Differing statutory objectives of national regulators led to varying levels of complexity in the risk frameworks produced. The risk scoring system also varied, with risk assessment playing a central role in the final scores produced in one regulator (UK Financial Services Authority), and the final score dependent upon expert judgement in another (Canadian Office of the Superintendent of Financial Institutions – OFSA). Thirdly, the role that risk assessment plays in allocating regulatory resources to regulated financial institutions differs across the three countries. Whereas the Australian Prudential Regulation Authority (APRA) and UK Financial Services Authority rely on risk assessment to determine their relationship with regulated organisations, this goes against OFSA’s legal mandate that all consumers should expect a similar level of regulatory oversight of their financial services. Finally, Black discovered that whereas the UK Financial Services Authority has a legal mandate that includes extensive rule making powers, OFSA and APRA do not. This in turn affects the risk framework they utilise as both OFSA and APRA use it to allocate supervisory resources. The FSA also uses it to set the strategic direction of the regulator.

Krieger (Krieger 2012) investigated the risk-based approach to flooding in Germany and the UK and found a number of institutional differences, defining them as “political culture and norms; style of public administration; and state culture”. With regard to political culture and norms, Krieger’s research indicates that Germany has a “protective state” culture, which demands of the state a significant responsibility for the well-being of its citizenry. There is a need to provide a high level of protection to all citizens no matter the situation of the risk (e.g. flood in a secluded farm vs. a busy city centre). This appears to conflict with a risk-

based approach that prioritises regulatory action based upon the size of the risk posed. Understanding the normative foundations of England's risk-based approach to flood defence proved prohibitive due to the lack of a written constitution. However, the Power's audit society appears to be clearly evident and risk-based tools are utilised in order to provide economically grounded objectives when targeting flood risks. As Krieger concludes, "the normative foundations of England's polity promote an economic and defensive rationale for the use of risk in flood management" (Krieger 2012).

Krieger (2012) defines Germany's style of public administration as "juridified": "Any administrative intervention must be based on formal law and is subject to judicial review through a specialised court system". As administrative decisions are open to judicial review, introducing the concept of uncertainty into policymaking opens up the decision to legal challenge. Germany therefore appears to have a split-level approach to risks, that of "danger" or "no danger" – any risks that are deemed tolerable but have a certain degree of uncertainty will most likely be challenged as the state is failing to provide necessary levels of protection. In the UK, there are not the same constitutional or judicial constraints, allowing for greater acceptance of uncertainty within policymaking. Indeed, as the UK implements managerial, administrative doctrines (such as NPM) in its review process for flood management, risk-based approaches are actively endorsed and implemented.

Finally, the structural characteristics of flood risk management in England and Germany show a significant amount of fragmentation. Within Germany, the federal system of the country leads to multiple layers of governance between semi-autonomous Länder and the federal government. This complex regulatory arrangement between national and local levels reduces the need for blame-deflection, "In complex polities like Germany's, responsibilities are shared and accountability opaque. This can be argued to reduce blame attribution to specific state actors, and attenuates public scrutiny" (Krieger 2012). Structural fragmentation of flood management in England also exists but with a different outcome. With responsibilities split between Defra (policymaking) and the Environment Agency (operational responsibility), as well as economic oversight by Her Majesty's Treasury, fragmentation is evident. However, unlike in Germany, responsibilities in England are clearly distinct, leading to regulators having to understand the institutional logics of other stakeholders involved in flood management, whilst also being exposed to blame attribution.

These studies show that the application of risk-based regulation is not as simple as it first appears. Although the policy domains investigated above claim to be risk-based in their approach to regulation, country-specific and agency-specific factors contribute to diversity in application. There appears to be a plethora of drivers that contribute to this perspective, from constitutional norms to regulatory structure; legal mandates to risk scoring systems. This presents problems for supranational bodies (such as the OECD or WTO) that hope to implement risk-based regulation as a universally applied concept and is especially problematic in regard to the federalised nature of the EU, which has put risk-based approaches at the heart of many of its regulatory drives towards harmonisation across Member States. Food safety is one area where the EU seeks to implement high levels of harmonisation with risk-based approaches, and the doctoral research linked to this thesis will aim to show the successes and challenges faced in such an endeavour.

2.9 Conclusion

In conclusion, it is clear to see that risk-based approaches are being applied to a diverse range of regulatory issues. In framing governance from a risk perspective, it is possible to target regulatory action in a more considered and effective manner. The “command and control” methods of regulation have been replaced by a more nuanced palette of controls based subjectively on the risk at hand. Risk-based approaches appeal in the current economic climate especially, as it is hoped that such targeted approaches not only reduce burdens on business but more effectively organises regulatory action, essentially providing more bang for one’s buck.

However, there is a range of problems that risk-based regulation has not solved, implying that it cannot be seen as a sole mode of governance but more as a strategy to apply within a larger regulatory toolkit. Furthermore, risk-based regulation has inherent problems. Key issues here include the need to rate risks, the effect of public perception on risk regulation, issues of entrainment, regulating risk in uncertainty and squaring the objective nature of risk assessment with the subjective nature of risk management. These issues demonstrate that risk regulation is still a relatively nascent field. More extensive research needs to be conducted in order to further explore, and possibly find solutions, to these issues.

Despite the flaws mentioned, risk-based regulation is a growing field. It is hoped that through the practical applications of risk-based approaches, some of the issues presented here can be

addressed. Risk-based regulation does offer an attractive new paradigm for regulators, but they must be wary of its inherent weaknesses.

Chapter 3: Methodology

3.1 Introduction

Risk-based regulation within the European Union is becoming more widespread as the tools of risk analysis continue to provide regulators with a means to direct their resources and establish priorities of action. Food safety in the EU is indicative of this, with risk-based approaches increasingly being applied, as regulators seek to highlight and mitigate risks along the food chain. This evolution in food safety regulation raises some important research questions. Although policy documents within EU food safety point to a greater reliance on regulating through risk, to what extent is the EU food safety regime risk-based? Furthermore, how are the risk-based approaches championed by the EU being implemented by regulators tasked with ensuring the safety of our food in the UK and Germany? Finally, do risk-based approaches support the harmonisation of food safety regulation across Member States? As such, three aspects of European food safety are to be investigated: EU implementation of risk-based approaches as indicated by the control of food imports; national and local risk appetites as shown through the control of food hygiene in food businesses in the UK and Germany; and the application of food hygiene barometers in the UK and Germany as local level initiatives that reflect the extent to which local enforcement is risk-based. The research for this thesis was based upon documentary analysis of both contemporary and historical documents, as well as qualitative in-depth interviews with 70 respondents involved in providing or overseeing food safety within the UK, Germany and across EU institutions.

This thesis is concerned with understanding the application of risk-based approaches to enforcement activities in the EU, the UK and Germany in relation to food safety. As has been described in the previous chapter, the language of risk has been increasingly utilised within the EU regulatory sphere across a range of policy domains, including food safety. The explicit drive for more risk-based approaches to enforcement practices is a clear manifestation of the role of risk in regulation. This thesis posits that such a clamour for risk-based approaches to food safety regulation is predicated upon three main pathways. The first concerns previous food safety incidents and the damaging effect on regulators they have had. Not only do regulators want to apply systems of control that ensure that risks are identified and reduced, but risk-based approaches offer a distinction of what *can* be regulated and what *cannot*. Through the clear delineation of which risks fall under their remit, regulators are

colonising policy domains through the language of risk, helping to better exert influence. Conversely, by stating which risks do not fall into their remit, regulators cannot be held accountable when a hazard occurs outside their predefined area of control. The second pathway is related to trends in governance and the current economic malaise. With limited resources, hazard-based approaches to enforcement are becoming increasingly infeasible. Hazard-based enforcement is where the presence of a hazard is sufficient reason for regulatory enforcement, whereas the risk must be determined in a risk-based approach to determine action. In theory, risk-based enforcement will diminish enforcement workloads as certain hazards will be characterised as posing insufficient risk to warrant any action. Risk-based approaches should allow for better targeting of resource, prioritising efforts on risks determined to be larger. Finally, from a geopolitical standpoint, risk-based approaches offer a universal regulatory language, suited to European harmonisation. The claim here is that due to the rigorous scientific evidence that underpins risk-based approaches, dissent is reduced and the regulatory outcome of such approaches can be applied more easily across a socioeconomically diverse collection of Member States.

However, what is less well understood is the risk appetite that Member States have for the EU promotion of risk-based approaches, and how the EU's own risk appetite might transmit to a Member State level. Relatively specific to food safety, the EU has greater oversight of local enforcement matters than in other policy domains, as it tries to ensure the safety of food along the food chain, from farm to fork. EU regulations therefore extend from the Commission, through to national competent authorities, and then further to regional and local authorities. This extended regulatory pathway means that it is essential that any investigation of risk appetites in relation to food safety must occur at all three levels, and be aware of the effect that an EU drive for harmonisation will have on each stage of the regulatory pathway.

3.2 Risk regulation regimes

To support comparative analysis of the food safety regimes across the UK and Germany, the risk regulation regime approach has been utilised, as introduced by Hood et al. (2004). This approach recognises the “complex of institutional geography, rules, practice, and animating ideas” (ibid) of regimes, which goes further than the traditional view of formal governmental action, and aids in the highlighting of other informal regulatory agents and activities.

Essentially, the risk regulation regime approach is concerned with the ways in which regulation is organised. The approach goes beyond the basic determination of rules, as it seeks to understand the underlying reasons for the establishment of those rules, and how they are reflexively shaped by practices, cultures and norms. Furthermore, formal rules are often complemented with informal mechanisms of control, as non-state actors play an important role in regulatory action and reform. These underlying mechanisms and arrangements should identify the variety of risk-based approaches, and how they have been manifested in different regulatory settings.

The risk regulation regime approach ensures that for comparative analysis, aspects of regulatory regimes are compared like with like, as it breaks down the functional aspects of a regime into information gathering, standard setting, and enforcement stages. This is of benefit to this doctoral research, which focuses on aspects of enforcement. With enforcement practices, the risk regulation regime approach allows for the study of the institutional architectures of enforcement, its practices and cultures, and how the outcomes of enforcement correlate with the expectations of standard setting.

The risk regulation approach is applicable to the study of food safety regulation as its system approach helps clearly delineate the different facets of a regulatory regime, allowing for greater clarity in the choice of sub-regimes. Once a selection has been made, the approach aids comparative analysis of food safety regimes in the UK and Germany, as it indicates how differing institutional architectures, norms and cultures shape the adoption of risk-based approaches in these regimes.

3.3 Case selection

For investigating the challenges of implementing risk-based enforcement, food safety offers a very compelling case. Fundamentally, this is because food safety is an issue that affects everyone. We have always had to eat, and governments have always sought to regulate the trade and consumption of food. This makes food safety risks, “old” risks. While a lot of the discourse on risk focuses on how risks have changed throughout time, from environmental risks attributed to “acts of God”, to technological risks attributed to “acts of man”, food safety risks have always been apparent. This is why it is fair to say that food safety risks have always been seen as a traditional public “bad”. As a result, food safety regulation today is one

that is characterised by a host of interest groups, from local consumer groups that come from a public health angle, to huge multinational corporations that seek to facilitate the global trade of food. Mixed in amongst these actors is a wide array of government regulators, providing oversight along the entire food chain, from farm to fork. And, in order to ensure the safety of the food that lands on our plate, governments need to understand and be aware of a huge range of differing risks that can potentially impact at numerous points along the food chain.

This thesis is predominantly concerned with the enforcement of food safety regulation, to allow for detailed comparative analysis of an aspect of the food safety regime where numerous risk-based approaches have been discussed and implemented. As discussed in Chapter 1, the standard setting expectation is clearly defined within the EU GFL that food must be safe. Yet the EU has also been equally clear about the role of risk analysis in ensuring the safety of food. Therefore, the study of enforcement practices shows the extent to which risk-based approaches have been implemented in achieving the EU's overall goal of safe food. Such research will also show the extent to which risk-based approaches may contravene the stated goal of safe food. For example, simply because a standard requires or suggests a risk-based approach, it doesn't necessarily mean that the outcome will be as anticipated by the standard-setting body. Such a situation is especially pertinent within the EU, where Member States are required, either directly or indirectly, to implement European standards.

The EU provides an especially interesting subject for risk-based enforcement, as it seeks to deal with the vast array of food safety risks across a population of more than 500 million people. Today, the EU tries to achieve this by implementing a series of harmonising regulations, as it tries to guarantee the same level of safety across a socio-economically disparate set of Member States. Relatively recent food safety incidents, such as antifreeze in Austrian wine, dioxin in animal feed, and the BSE crisis, led to an institutional reorganisation of the European Food safety regime at the turn of the century. Complementing the harmonising dynamic, the EU has championed the use of risk-based approaches in the food safety domain, to help deal with emerging and re-emerging risks, and ensure that another international food safety crisis does not occur.

In a policy domain so heavily harmonised by European law, it would be reasonable to assume that a comparison of the UK and Germany would not show much difference in how risk-based approaches are adapted at an enforcement level. Not only are their food safety laws harmonised, but both countries are wealthy industrialised nations that have been a part of the EU since its original inception as the European Economic Community (EEC). Unlike Member States that have recently joined the EU, and who must undertake a series of regulatory reforms in order to be consistent with European food law, the UK and Germany have had ample time to ensure the correct level of legal and regulatory compliance. Furthermore, both countries have been enthusiastic proponents of risk-based approaches, as discussed in Chapter 1. However, the expectation that both these countries have adopted similar risk-based approaches under harmonised law has provided the yardstick for analysis of their enforcement practices. Any substantial differences in the implementation of risk-based enforcement help to show the drivers and challenges in implementing risk-based approaches. If the analysis was done on new Member States, there would be no expectation that enforcement practices would be harmonised and misplaced, and so it would be much harder to identify any variance from the norm that the EU is trying to present with regard to food safety.

Analysis of the institutional arrangements of the two countries helps in identifying drivers and constraints to risk-based approaches. The two countries have different organisations dealing with food safety, and different traditions when it comes to guaranteeing the safety of food. Of particular importance to the discussion of food safety is the fact that the two countries have differing jurisdictional and legal traditions. Germany contains a collection of semi-sovereign *Länder*, or states, that have competency for the enforcement of food safety. The UK on the other hand, despite local authorities carrying out enforcement activities, is far more centralised. The requirement to guarantee public health in Germany is codified in its constitution, the Basic Law. In contrast, the UK has no written constitution, and is reliant upon case law to help set the level of public health required. Fundamentally, there may be differences in how (and how easily) it is to implement risk-based enforcement practices through a fragmented and constitutionally juridified country such as Germany, and a centralised country such as the UK which may have less fixed legal recourse than Germany.

3.3.1 Selection of case studies within supranational and national food safety regimes

Despite the regulation of food safety in the EU being packaged as a harmonised set of legislation right along the food chain, in reality it is a highly complex matter of interrelating sets of supranational regulations and directives. Regulation of food sold on the EU market can cover multiple factors such as the storage of that food, its handling, the food's packaging, its labelling, the composition of ingredients and any certification that is required to confirm its nature and intended use. EU food safety regulation is applied from the production of the food, through its processing, transport, sale and consumption. This holistic approach concerns not just the Member States of the EU, but also third countries that are looking to export to, or import from, the EU.

As the farm to fork nature of EU food safety indicates, its regulation is an all-encompassing policy domain that takes into account the huge diversity of sub-regimes. To analyse all of these regimes would be far beyond the achievable scope for a PhD thesis. If the case studies are poorly selected, the utility of this thesis will become diminished as analysis becomes swamped by crisscrossing regulatory frameworks. At the same time, it is important to capture the dynamic between supranational, national and local regulation that has been previously discussed. The selection of such regimes is of great importance to representatively provide analysis of EU, Germany and UK food safety regimes overall. To ensure this, analysis has occurred along the entire regulatory pathway of the EU food safety regime. Therefore, as previously mentioned, the research focused on three aspects: EU approaches to risk-based approaches as indicated by the control of food imports; national and local risk appetites as shown through the control of food hygiene in food businesses in the UK and Germany; and the application of food hygiene barometers in the UK and Germany as local level initiatives that reflect the extent to which local enforcement is risk-based.

First, the EU's eagerness to implement risk-based approaches within food safety is discussed (Chapter 5). Discussion centres on how the EU can guarantee, as indicated in its general food law, the safety of food sold on the European market, while utilising risk-based approaches. This includes how the EU can set acceptable levels of risk across all 28 of its Member States, given their own individual risk appetites. The sub-regime of food imports is used as a case study here, as imports show the greatest involvement of EU oversight with regard to

enforcement, with the need for highly harmonised set of controls to ensure the borders of the EU are consistently managed.

The second case study is concerned with national and local enforcement practices within the UK and Germany (Chapter 6). This case study will help reveal how EU expectations on local food safety enforcement will manifest themselves within two different Member States. Even though such enforcement controls are harmonised, differing traditions and norms, as previously discussed in this chapter, will come to light and show how implementation of the same standards may differ. This chapter will also show how local enforcement practices may not only reflect or differ from EU-level expectations of food safety, but also from historical national preferences for food safety. This has implications for the maintenance of a highly harmonised EU food safety regime.

Finally, the third case study will investigate the implementation of food hygiene barometers in local food businesses within the UK and Germany. In both countries, food hygiene barometers have started very much as local initiatives, and have either become a national initiative (the UK) or remained more fragmented and local (Germany). Here we are at the end of regulatory pathway, as discussion of the implementation of barometers is largely at local and national levels. Indeed, the implementation of food hygiene barometers is one of the few areas of food safety enforcement over which the EU does not yet have direct supervision, other than ensuring that the barometers are compatible with EU food law on the hygiene of food businesses. Without the harmonising influence of the EU, this case study will help highlight the context of food safety practices within the two countries. Finally, the barometers case study highlights the importance of non-state actors as defined in the risk regulation regime approach, as these barometers intend to better inform consumer choice of food business.

3.4 Research methods

This section will outline how the empirical evidence for this thesis has been captured, to elicit the formal positions of the target organisations, as well as the practices, cultures and interpretations of standards in order to ascertain the extent to which risk-based approaches are manifested within the enforcement of food safety. To achieve this, documentary analysis has been complemented by a series of in-depth qualitative interviews of respondents working

along the regulatory pathway, from supranational standard setting, to local enforcement. Yin (2013) argues that the use of multiple sources of evidence allows for the analysis of historical, attitudinal and behavioural issues to be addressed. As such, the in-depth documentary analysis and interviews conducted along the EU food safety regulatory pathway should greatly aid the comparative analysis of the three case studies chosen.

A qualitative approach was adopted to gain an in-depth knowledge of the sub-regimes investigated regarding risk-based decision making. Quantitative data allows for a representative view, as a much larger portion of a population can be targeted than is possible with in-depth qualitative interviews (due to time and resource constraints). However, qualitative data gathering can provide powerful information for the researcher. Cloke et al. (2004) argue that such an “intensive” form of data allows the researcher to “find the causal processes and mechanisms behind a particular event”. Furthermore, in-depth interviews allow the researcher and the respondent to work through questions together, “which begin as the property of the researcher but which become co-owned and co-shaped in the unfolding interactivity”. Therefore, the researcher is able to gauge respondents’ answers better than through a closed questionnaire, as open and semi-structured interviews give the respondents a voice in which to further elaborate upon their views and question the assumptions of the researcher. A face-to-face or telephone interview allows for the direct interpretation of, and feedback to, information provided by the respondent. Conversely, an indirect form of data gathering (such as an internet questionnaire) is secondary in nature and therefore does not allow for such direct interpretation and feedback.

3.4.1 Analysis of documentary sources

Documentary research for this thesis was conducted across a wide range of key stakeholders within the UK, Germany, and the EU. Such research included the study of primary sources of data, predominantly in the form of regulations, policy documents and reports produced by regulators, the food industry and consumer interest groups. In order to understand and analyse the historical context of food safety regulation in the UK, Germany and the EU, historical overviews were studied. This research helped provided the necessary context for the current state of food safety regulation, and combined with the documentary analysis of contemporary regulation, led to several advantages. The first was that the scope for this thesis could be clearly set. Food safety regulation is a very complex policy domain, represented by

a plethora of sub-regimes which are active at multiple points along the food chain.

Documentary analysis allows for a clear overview of these sub-regimes and the levels of interaction between them. As a result, sub-regimes can be selected that are most applicable to the conceit of this thesis, namely the application of risk-based approaches to the enforcement of food safety. The risk regime approach provides a useful methodological framework here, as it helps compartmentalise the different aspects of a regulatory regime, and allows greater focus, in this case, on enforcement.

3.4.2 Interviews

The use of qualitative interviews was central to the evidence compiled by this thesis. To capture practices, cultures and norms that may go beyond what is elicited in documentary analysis, semi-structured interviews were organised across the UK, Germany and EU institutions related to food safety regulation. Interviews allow for the elicitation of personal perspectives on formal rules and procedures (Weimer & Vining 2015). Such qualitative interviews are especially pertinent when investigating enforcement activities, as there may be a degree of disconnection between the formal expectations articulated at a standard setting level, with the “reality” of the situation when a standard is enforced. The semi-structured nature of the interviews allowed for a good degree of depth in the answers that respondents gave, while having sufficient direction to allow for comparison of respondents across the case studies selected for this thesis. Those interviewed were given the flexibility to explore topics that may not have been presented in the questioning, but were deemed by the respondent to be useful to the research, as was clearly set out at the beginning of each interview. This enabled a greater level of understanding of the policy domains explored in this thesis, as there was no assumption that all important avenues of research had been definitively determined in the documentary analysis. As such, the interviews informed further documentary analysis, and this helped in the identification of more people to interview.

The initial selection of interview respondents was based upon documentary analysis conducted by the researcher. Further respondents were selected through the process of “snowballing”, whereby initial respondents recommend others who would be relevant to the research at hand. All respondents, whether initially selected or recommended, were emailed. The invitation email contained an information sheet outlining the overall premise of the research and stating what was expected at interview. With the exception of two interviews,

which were conducted by telephone due to the preference of the respondent, all interviews were conducted face to face. Interviews were recorded with the permission of the respondent, and detailed notes were taken throughout all the interviews. The recordings were then part-transcribed, to allow for rapid assessment of the interviews, in order to ascertain whether information relevant to the thesis was being collected. This allowed for tweaks to be made to the research agenda as the interviews progressed, in order to ensure that the interviews were directed in the best way possible. The interviews were conducted from May 2013 to May 2015. This time period allowed for sufficient reflection on the interviews conducted, and greater flexibility in order to match the availability of respondents. Where necessary (due to time constraints imposed on the interviews) or beneficial (following up on information provided in the initial interview), follow-up interviews were conducted with certain respondents. This ensured that important empirical data was not precluded from investigation due to the condensing of often complex discussions into one conversation.

With almost all the interviews conducted, a workshop in Paris was co-organised in April 2015, which included food safety enforcement officers from the UK, Germany, France, the Netherlands, and Luxembourg, as well as academics working on risk-based regulation. This occasion served as an excellent opportunity to test hypotheses that had been formed as a result of both the documentary analysis and the interviews conducted. With enforcement officers from both the UK and Germany present, it also allowed for direct comparison of enforcement practices, helping to highlight key differences. The presence of enforcement officers from other EU Member States also put the differences between the UK and Germany into the perspective of an overall EU framework.

3.4.3 Selection of respondents

With three sub-regimes being investigated across the UK and Germany, and more broadly across EU institutions, respondent selection was critical. Due to the high number of organisations contributing to the data gathering process, only a small number of representatives (~1-5) were interviewed from each organisation. These representatives were “champions” of the organisation, as they were charged with indicating the extent to which their organisation is utilising a risk-based approach, and their own personal views on the efficacy of such approaches. The following is a list of organisations that were interviewed (see Appendix 1 for the number of respondents interviewed):

- Respondents from all EU institutions directly dealing with food safety were selected. These included DG SANTE, the European Food Safety Authority (EFSA), and the Health and Food Audits and Analysis Directorate (which at the time of interviewing was the Food and Veterinary Office – FVO).
- National competent authorities for food safety were selected in the UK and Germany. In the UK, this included the Food Standards Agency (FSA) and the Department for the environment, food and rural affairs (Defra), as well as an executive agency in Defra, which could provide detail on the imports of food of animal origin, the Animal and Plant Health Agency (APHA). In Germany, this included the Federal Ministry of Food and Agriculture (BMEL), and institutions that fall under its portfolio, namely the Federal Institute for Risk Assessment (BfR) and the Federal Office of Consumer Protection and Food Safety (BVL). Finally, due to a recent report on the state of food safety regulation in Germany, the Federal Court of Auditors (Bundesrechnungshof), was also selected for interview.
- At a regional level in Germany, six out of the sixteen states (Länder) were visited – Baden-Württemberg, Bavaria, Berlin, Hamburg, Lower Saxony and Saxony. Respondents were selected to cover the regional aspects of food safety regulation, as well as enforcement of food business at a local, district level. In Baden-Württemberg, the regional risk assessment laboratory, the Chemical and Veterinary Investigation Office, Stuttgart (CVUAS), was also selected.
- At a local level in the UK, eight different local authorities were interviewed in England – Huntingdonshire, Great Yarmouth, Waveney and Suffolk Coastal, Horsham, Ipswich, Rother and Wealden, Brighton and Hove, and Norwich. The Chartered Institute for Environmental Health (CIEH) was also selected, as it plays a coordinating role across local authorities, and underpins the training of Environmental Health Officers in the UK.
- Border inspection posts (BIPs) in the UK and Germany were selected. These included Heathrow Airport, Felixstowe Port, and the London Port (Tilbury) in the UK, and Hamburg Port and Munich Airport in Germany.

- Food industry representatives were also selected across the UK, Germany and the EU. On a supranational level, the International Meat Trade Association (IMTA) and FoodDrinkEurope were selected. With regard to Germany, respondents from the German Federation for Food Law and Food Science (BLL) were interviewed. In the UK, respondents from Moto hospitality and the British Retail Consortium (BRC) were interviewed.

3.4.4 Selection Rationale

Due to the presence of numerous supranational and national standard setting and enforcement bodies, respondents needed to be carefully selected. On an EU level, it was relatively straightforward to select the three organisations that were principally responsible for food safety, namely DG SANTE, EFSA and the FVO. However, as these organisations had a broad range of competencies, clear interview expectations were communicated in order to identify the correct respondent. Discussions at DG SANTE helped reveal the European Commission's overall approach to food safety and how risk-based approaches are expected to accommodate such an approach. DG SANTE also oversees the tightly harmonised EU food import regime, so that expectations specific to food imports could be solicited. The FVO provided a useful target for interviews, as through its auditing of Member States, it oversees the extent to which standard setting expectations at an EU level are implemented at a Member State level. The FVO therefore provided an important link to the regulatory pathway between EU standard setting, and national interpretation and enforcement of those standards. Finally, through its risk assessment competency, EFSA allowed for a general discussion on the extent to which risk-based approaches underpin EU food safety directives and regulations.

With Germany, geopolitical fragmentation is clearly apparent in the case of food safety as each state (Land) has competency for the enforcement of food controls. This means that Germany effectively has a two-tiered system, with the federal level interpreting and implementing EU directives and regulations into German law, and the Länder overseeing the enforcement of both federal and Länder standards. The historical context of Germany also provides another important distinction – that of the former West and East German governments. In order to capture both historical and contemporary layers of fragmentation, Länder were carefully selected. The selection included one of the so-called Eastern “new

Länder” (which joined following the reunification of Germany in 1990), Saxony, and a Land that was segregated into West and East administrations, Berlin. The selection also took into account administrative differences between different Länder. Most German Länder are subdivided into administrative districts (*Kreise*), and further down into municipalities (*Gemeinden*). However, the city-states of Berlin and Hamburg do not have such subdivision. Finally, Länder selection took into account differences in the economic outlook of various Länder, with the traditionally wealthier Länder of Bavaria, Baden-Württemberg and Hamburg compared with less wealthy Länder such as Saxony and Berlin.

Food safety regulation in the UK is far more centralised than its German equivalent. However, the devolved administrations of Scotland, Wales and Northern Ireland means that the picture is somewhat more complex than first thought. While the documentary analysis of this research included enforcement practices in devolved administrations, interviews were only conducted in English local authorities. The reasons behind this decision included considerations of feasibility and aiding comparative research. Visiting and suitably capturing three devolved administrations will have reduced the overall feasibility of the thesis, and diluted any comparative analysis of regimes in Germany and the UK, as standard setting functions would need to be discussed across no fewer than five administrations (Germany, UK, Scotland, Wales and Northern Ireland). With the majority of the UK’s population living in England (approximately 83.9%), England was chosen as a suitable comparator for Germany in terms of broadly similar populations. The selection of local authorities within England also reflected the difference between city authorities, such as Brighton and Norwich, and more rural local authorities, such as Huntingdonshire. The selection also took into account the differing organisation of the authorities themselves, with certain authorities having been joined together (whether for efficiency reasons or because of their small size individually), and others continuing to operate as single authorities. The joint authorities interviewed, such as Rother and Wealden, have a mix of institutional memories, which revealed different drivers and constraints to a harmonised system of food control across England.

Finally, members of the food industry were interviewed, as under the GFL, the food industry must take responsibility for providing safe food. The way in which regulatory enforcement practices take such a responsibility into account, and the level to which food businesses feel that enforcement is risk-based, is of importance to the food safety regime. As such, food

business associations that operate within the UK and Germany, as well as across the EU, were targeted for interview.

All the research conducted was compliant with the King's College London Social Research Association's Code of Ethics, and ethical approval had been granted in advance of the interviews. All interviews were conducted with the respondent's informed consent, and all respondents were provided with an information sheet setting out the PhD research, relevant contact details, and ethics guidelines.

3.5 Issues with methodology

As respondents were either selected by the researcher or recommended by other respondents, they did not directly self-select. It is hoped therefore, that any bias associated with self-selection will have been avoided. However, there are always bias issues with using "snowballing" as a means to select further interview participants, as it is conceivable that one respondent may recommend another who shares the same views and outlook. It is hard to avoid this issue. However, the majority of respondents selected for interview were identified by the researcher.

Due to the small sample size of respondents interviewed in each organisation, interviewing "champions" of an organisation runs the risk of resulting in a misrepresentative picture of the organisation and its views. As such, there was a greater need for the researcher to be aware of any discrepancies between a respondent's answers and the policy direction of his/her organisation and conceivable outcomes within the target area. Cloke et al. (2004) advise that due consideration be given to whether the respondent is acting and providing information in a formal capacity as the representative of an organisation, or in a personal capacity.

While the researcher has working knowledge of German, and some of the documentary analysis was conducted in German, all interviews were conducted in English. This may lead to criticism that implicit meanings may have been lost in translation. However, the clear majority of German respondents were happy to speak in English (as were non-native English speakers in EU institutions) – due to the Europeanised nature of food safety regulation, English has become a common language spoken between regulators of different Member States. Translators were provided for two respondents, who felt they could not suitably

articulate their answers in English. Furthermore, the argument that certain meanings are lost in translation, occurs whether it is the interviewer or the interviewee having to translate, making this an ongoing concern for any piece of comparative research conducted in more than one language.

Recording the interviews could also prove problematic. Even when respondents agree to be interviewed, having a recording could affect them in several ways. This includes becoming self-conscious as a result of the presence of a recording device, and also providing less personalised answers as the respondent is aware that his/her opinions are being recorded. To overcome these potential difficulties, the respondents were assured of the confidentiality of their accounts given, told that their data would be anonymised and given the option to turn off the recording device at any time in the interview. The argument for having a recording of the interview in the first place is that full transcripts can allow for a much deeper analysis of the interviews, as opposed to purely analysing the researcher's notes. There were three respondents who asked for their interview not to be recorded, requiring the use of detailed long-hand notes to compensate for not being able to analyse a recording after the interviews were conducted.

3.6 Conclusion

This chapter has set out the methodological framework underpinning this thesis. In the selection of three case studies – food imports, national and local enforcement practices, and food hygiene barometers – the full length of the regulatory pathway in the EU food safety regime can be identified. By using the risk regime approach to compartmentalise regulation and focus on enforcement practices, the thesis has a clear focus, rather than trying to undertake too much, which would have resulted in vague assertions of little epistemological use. Both the documentary analysis and the interviews draw strongly on a qualitative approach, as the in-depth detail gleaned from enforcement practices, cultures and norms have helped highlight differences between expectations at standard setting and the “reality” of enforcement.

This chapter has explained the methodological approach to assessing differences in the application of risk-based approaches in Germany and the UK, within the context of the EU

food safety regime. The following empirical chapters present the evidence gathered as a result of the methodological approaches adopted.

Chapter 4: Food governance traditions and modern governance of food safety

4.1 Introduction

Simply put, ladies and gentlemen, in the minds of the citizens of Europe, safety is the most important ingredient of their food. David Byrne, EU Commissioner responsible for Health and Consumer Protection

How we produce, sell and prepare our food has led to a great variety of food governance issues. Whether it be the purity or quality of the food, its cultivation or destination; its nutrition or safety; food, rather understandably, has been of great importance to the sustenance and sustainability of nation states. In the great pantheon of risks we face in our daily lives, those relating to food must feature somewhere near the top of our priorities. After all, food is essential to our very existence, so if the food that sustains us turns out to make us ill, this is surely a cause for great concern. The above quotation from Commissioner Byrne came at a critical time when the BSE crisis was in full swing, and the nation states affected were scrambling to deal with a full-blown epidemic. Yet at the same time, because food is so intrinsically linked to our daily routines, any unforeseen detriments associated with its consumption can also be played down as the following story makes clear (Nestle 2003):

In the early 1970s, a time when food safety was becoming a matter of public debate, my young family went to a dinner hosted by a colleague. I don't remember much about the party, but its aftermath remains vivid. Within hours, all but one became violently ill. I will spare the details, as nearly everyone has had a similar experience. A flurry of telephone calls the next day made it clear that we were not the only ones who suffered after that dinner. In retrospect, what seems most remarkable about that event was how ordinary it was. We survived. We felt better in a day or two. We did not report our illness to health authorities, and neither did anyone else.

So, food safety occupies a highly complex mixture of normative and cultural values. Ensuring safe food is to ensure that we can rely on the very fuel that is needed to sustain us. Yet at the same time, in the Western world, eating is such a mundane and normalised activity, an entire family can be violently ill and take the matter no further. Food safety is as critical to protecting an activity that is core to our very existence, as it is mundane in dealing with an activity all of us partake in daily. It indicates the potential that food safety incidents have to cause heightened levels of fear (both founded and unfounded), such as during the BSE crisis, yet on a day-to-day basis hardly features in our conversations. This dichotomy provides a great challenge to those who seek to regulate the domain. For thousands of years, regulations have sought to protect the cultural currency of food, the rise of fraudulent practices, and the inherent safety of the food we eat. Today, within the EU at the very least, the stakes are high. After all, the EU General Food Law (GFL), as laid out in 178/2002, states that all food sold on the market must be safe. As a central mantra, one can't get more definitive than that. Yet that mantra brings new issues to the fore: how to set such a high level of food safety, and how it needs to be enforced. This chapter addresses those topics by examining how the emergence and evolution of complex webs of food safety regulation have followed distinctive national patterns in the two countries under investigation, the UK and Germany.

4.2 The long history of food

Many of the food governance issues that are posed to regulators today have existed for millennia. Although concepts and processes such as globalisation, food miles, and the mass production of food have a relatively modern resonance to them, protecting the food supply always has been, and always will be, an overriding necessity. There is documented evidence going back to 6000 BC indicating issues of spoilage and the transmission of diseases from food to humans (Jay et al. 2008). Phoenician inscriptions pointed to a law that prohibited people from casting spells on their neighbours' wine (Loschelder 1987). As the Roman Empire expanded, feeding the empire's burgeoning populace became more important, with civil laws introduced to guard against the adulteration of food (Roberts 2001). In Britain, the first law to regulate food production and sale was passed in 1266, known as the *Assisa Panis et Cerevisiae*, which sought to regulate the price, weight and quality of bread and beer.

Although scientific methods had been developed to measure weight, this was not the case for testing quality (Dawson 2014):

Food quality was judged using subjective means, which included appearance, aroma and taste. A popular method of testing ale quality was conducted by Ale Connors, who were the equivalent of the modern Customs and Excise. The ale would initially be tasted and then poured on to a wooden bench or stool. The inspector would then sit on the bench wearing leather breeches. After about a minute, he would stand up and see if the ale stuck to his breeches. If the ale stuck, it was considered good quality.

Issues of quality persisted, and were reinforced by fears of adulteration. Trading standard laws relating to food can be traced back to the 13th century (Lang 2006). In Germany, the Middle Ages brought about specific purity laws, clearly stating which ingredients were permissible within certain food and drink products. The much-celebrated beer purity law of 1516, *Reinheitsgebot*, a law that still exists to this day, permitted only barley, hops and water in the production of beer. Before even this, a purity law for Thuringian Rostbratwurst in 1432 demanded that only pure, fresh sausage be used, and forbade the use of beef, internal organs, parasites and anything rancid (Whitlock 2007). The protection of the cultural heritage of Germany's beer and sausage goes back hundreds of years.

However, it is not until developments in the 19th century that we begin to see the basis for modern food safety law in the UK and Germany.

4.3 The evolution of UK food safety law and enforcement

The early evolution of food regulation in the UK was more concerned with protecting trade than dealing with the health of the consumer. Despite laws pertaining to the trade of food stretching back to the 13th century, prior to the 19th century, British law was relatively scarce on the subject of food safety. As Dawson (2014) argues, "early efforts to regulate quality standards in the Middle Ages were conducted by corporations of craftsmen, called the guilds. However, these were set up to protect the market rather than the customer or

consumer". For example, in 1858, twenty people died and more than two hundred were injured in Bradford when arsenic was accidentally sold instead of plaster of Paris (then used as a cheap substitute for sugar). When the proprietor who sold the arsenic was brought to court, manslaughter charges were dropped, as there was no law against such a type of offence. The local newspaper lamented, "The actual crime is that there is no law prohibiting the practice of adulterating foods".

It was not until the mid-19th century that UK government action regarding food safety developed significantly. Up until that point, however, food poisoning was not a concern. The advent of the industrial revolution certainly brought with it a range of food related problems, yet food poisoning as we know it was not recognised as one of them. Instead, authorities were interested in the adulteration of foodstuffs for sale throughout the UK.

The industrial revolution brought a population boom and the convergence of citizens in ever expanding cities across the country. Accompanying this was greater global trade in food as the British Empire took advantage of its burgeoning borders. Exotic foodstuffs were being imported from further afield and sold throughout the UK. This created new food markets but at the same time generated more hazards, as the food supply chain became more complex and new foodstuffs were introduced. Hardy (1999) notes that people's eating habits also changed: "Fast food and shop-prepared dinners are no twentieth century invention: they have their precedents in earlier urban societies". The changing nature of how food was consumed led to an exponential increase in food vendors, who brought a diverse range of different practices to food procurement and preparation.

At the same time, in the UK between 1815 and 1850, real incomes barely increased and agricultural prices remained high before free trade policies came into force. This encouraged unscrupulous activities, with food vendors selling cheap but heavily adulterated common foodstuffs such as tea, milk and coffee. For example, the poisonous *Cocculus indicus* (the fruit of the *Anamirta cocculus* plant) was used to replicate the bitter taste and intoxicating effect of beer. Hams and tongues were brushed with a mixture of borax, salt, creosote and red tar dye to make them appear well smoked. Food colourants, preservatives and flavourings were also a major cause for concern. As Collins (1993) records, "Prussian

blue, red lead, lead chromate, arsenite and carbonate of copper, sulphide of mercury and iron oxide were all well known in the food trades in 1850". Food poisoning, however, was not at the top of the political agenda in the 19th century. Indeed, food poisoning was not outlined in the UK until 1935 when MacNalty, the Chief Medical Officer of the Ministry of Health defined it as:

An acute gastro-enteritis due to the ingestion of food and drink which either contains living bacteria of species capable of setting up an acute inflammation of the alimentary tract... or contains irritative substances – "toxins" – produced by the growth and bacteria in food and drink.

It was not until the advances in bacteriology at the end of the 19th century, when different strains of bacteria could be separated and their effects identified, that food poisoning via food-borne organisms was suggested. For most of the 19th century, illness was not attributed to the preparation, putridity or presence of harmful toxins but to individual foodstuffs, as the following example in Hardy's history of food safety (1999) shows:

When cholera arrived in London in 1848, the citizens expressed their beliefs and anxieties very clearly in their food marketing – sales of fruit, vegetables, and particularly fish, plummeted and the city's costermongers, who depended on this trade for their livelihoods, were reduced to desperate straits.

Indeed, the development of industrial society made food-borne infections on a large scale a relatively novel phenomenon: "There are good grounds... for believing that food-borne infections were widespread in English society by the 1850s, and that this was a relatively new phenomenon, and the result of social change" (Hardy 1999). It was adulteration that promulgated a series of food Acts that superseded the medieval agricultural food regime. The first of these was the Adulteration of Food and Drink Act of 1860, which allowed for the appointment of public analysts (who still exist today, employed by local authorities or private laboratories), charged with analysing samples of food. However, the law did not contain any provisions for local authority sampling powers, and private individuals were expected to pay for any samples analysed. The Adulteration of Food and Drugs Act 1872

somewhat rectified the lack of enforcement powers by allowing “inspectors of nuisances” to acquire food samples.

This mention of “inspectors of nuisances” indicates an important development of the precursors to the modern Environmental Health Officer (EHO). These inspectors were a result of the work done by a Poor Law Commissioner, Edwin Chadwick, who conducted an inquiry into the causes of poverty. The inquiry found that people became poor due to ill health caused by a bad environment. Chadwick identified the need to improve sanitation and campaigned for the government to take corrective action. The government responded with the 1848 Public Health Act, which provided for the appointment of “inspectors of nuisances”, who were generalists tasked with looking at aspects of sanitation on a local level, of which food formed an important part. That generalist approach has set a precedent for inspectors through to the present day, as modern EHOs can deal with a range of areas from food safety to occupational health and safety; air quality to housing.

The 1872 Act added to the powers of these inspectors, not just by allowing them to acquire samples, but also through empowering them to prohibit food which was deemed “not of the nature, substance and quality” expected. “Nature” referred to the sale of foodstuffs as they claimed to be, and “substance” referred to ensuring that the food sold did not contain ingredients that the consumer would reasonably expect not to be present. The “quality” of food referred to whether it was rotten or mouldy, which might or might not pose a health hazard.

The 1875 Food and Drugs Act further boosted the enforcement powers of inspectors by allowing them to enter premises, inspect food and seize unfit food. However, these laws specifically dealt with chemical adulteration (Adulteration Acts 1860, 1872 and 1875) and unsoundness (Nuisances Removal Act, 1855). Explicit reference to the harming of health and the strict liability for the food business was made in the 1875 Act, but this concerned the adulteration of food, rather than its hygienic handling and storage:

No person shall mix, colour, stain, or powder, or order or permit any other person to mix, colour, stain, or powder, any article of food with any ingredient or material so as

to render the article injurious to health, with intent that the same may be sold in that state, and no person shall sell any such article so mixed, coloured, stained, or powdered, under a penalty in each case not exceeding fifty pounds for the first offence; every offence, after a conviction, shall be a misdemeanour, for which the person, on conviction, shall be imprisoned for a period not exceeding six months with hard labour.

While the 1860 and 1872 Acts had declared that food businesses could not *knowingly* sell injurious, adulterated or impure food, Fallows (1988) argues that it was only with the advent of the 1875 Act that the antecedent to today's strict liability with regard to the sale of unsafe food was created:

The law contained within the 1875 Act (and all subsequent legislation) is criminal law, not civil law, and is one of strict liability. The prosecution has no need to prove intent; earlier acts had used the term "...knowingly to..." This fact alone strengthened the law considerably.

As Fallows makes clear, the 1875 Act set a precedent for banning the sale of food that was deemed injurious to health, whether it be intentional or not. Food adulteration, though, was becoming less of an issue towards the end of the 19th century as free market forces, greater coordination along the food chain by large food suppliers and a significant increase in real wages ensured that food was cheaper to market and in general disposable incomes were much higher. That period, however, saw the discovery of foodborne organisms that caused illness, such as *Salmonella enteritidis* in 1888, and a consequent drive for regulatory action against food poisoning and the unhygienic practices that led to the spread of foodborne illnesses. However, commercial interests ensured that the profile of food poisoning was kept low, with increased bacteriological research into food poisoning the only tangible outcome at the beginning of the 20th century.

4.3.1 From adulteration to hygiene – food safety in the 20th century

It was, therefore, not until well into the 20th century that the narrow focus of food fraud and adulteration was supplemented by the consideration of hygiene practices¹. Advances in bacteriological science had firmly shown a causal link between hygiene practices and the incidence of foodborne infections. The Public Health Act 1925 required food businesses to have a standard of cleanliness, clean water and washing facilities; requirements that were strengthened by a series of subsequent Acts and amendments over the next couple of decades. Furthermore, shortly before the outbreak of the Second World War, a sweeping review of local authorities recommended the passing of a Food and Drugs Act that consolidated the previous adulteration Acts with an explicit commitment to highlighting and dealing with foodborne illness. This included the hygienic preparation of food and statistical record keeping of food poisoning outbreaks within local authorities. However, it was only after the Second World War and concern over food security and the hygiene of rationing that foodborne illness came to national prominence:

Regulation of the practices of bulk commercial food manufacturers, and changing cooking methods, presented new problems. Egg-borne salmonella poisoning received widespread publicity, for example, when incidents were traced to the use of bulk-imported American powdered egg. Moreover, rationing and communal feeding encouraged the practice of reheating foodstuffs, which had been far less common before the war, but which favoured bacterial survival and multiplication, especially where cooking involved large quantities of meat. (Hardy 1999)

Food-borne illness became more politically salient following the introduction of free healthcare at the point of delivery by the new National Health Service (NHS) in 1946, as a

¹ It should be noted that the control of slaughterhouses followed a slightly different trajectory from that of food businesses, with regulations introduced to curb the nuisance (for example, the run-off of blood and remains into the street) caused by the location of small slaughterhouses close to other shops and workplaces. The licensing and control of slaughterhouses, as well as the appointment of inspectors to oversee them, was introduced in the Food and Drugs Act 1938. Following the Second World War, the creation of larger slaughterhouses away from other businesses and homes, allowed for easier supervision and hygiene requirements.

much larger proportion of the population presented to general practitioners with the symptoms of food poisoning. This, coupled with mandatory notifications of food poisoning incidents at a local level, ensured that foodborne illness was at the very centre of food law. The result was the Food and Drugs Act 1955, which produced the first “code” for the general hygiene of food businesses. The 1955 Act stipulated the need for hygiene in relation to protecting public health, and ensured that the following provisions were made (HM Government 1955):

For imposing requirements as to the construction, lay-out, drainage, equipment, maintenance, cleanliness, ventilation, lighting, water-supply and use, of premises in, at or from which food is sold for human consumption, or offered, stored or prepared for sale, for human consumption (including any parts of such premises in which apparatus and utensils are cleansed, or in which refuse is disposed of or stored).

These requirements, and the hygiene code that was provided in the 1955 Act, remained largely intact through subsequent amendments to the law, appearing in the Food Act 1984 and the current Food Act 1990. An amendment in 1995 to the 1990 Act covered temperature controls for foods that were determined to be “high-risk”, i.e. foods that will allow the survival and/or growth of pathogens. However, hygiene requirements for food businesses have remained largely the same, with the 1955 Act’s code providing the underpinning logic for EHO codes of practice.

4.3.2 The institutional architecture of food safety following the Second World War

Responsibility for food safety has changed multiple times since the end of the Second World War. At that point, two ministries pertaining to food and its production existed – The Ministry of Agriculture and Fisheries, and the Ministry of Food. The former was predominantly concerned with serving and protecting the needs of the agricultural sector, whilst the latter was established due to the need to secure and ration food supplies during the two World Wars. By 1955, the need to ration was no longer a concern, and so the two ministries were merged into the Ministry of Agriculture, Fisheries and Food (MAFF).

By the 1980s, MAFF was facing pressure on two fronts – the first was because of neoliberal pressures placed upon Britain’s membership of the EU’s Common Agricultural Policy (CAP), underlined by a political environment that was hostile to market interventions through the CAP (Drummond et al. 2000; Lowe et al. 2003); the second by a string of high profile food safety incidents. The regularity of these incidents increased towards the end of the decade, with proportional levels of media coverage, which eroded the legitimacy of MAFF as public confidence began to dwindle. A notable indicator was the salmonella crisis of the late 1980s, when a junior health minister, Edwina Currie, claimed that most eggs produced in Britain were infected with salmonella. Not only did this lead to her swift resignation, but the culling of four million hens and the destruction of 400 million eggs. The government had to financially assist the egg industry, as sales plummeted. Throughout the salmonella crisis, MAFF was accused of siding with the food industry, instead of championing public health concerns. To make matters worse, in line with Thatcher’s government’s deregulatory approach, MAFF was perceived as increasingly ineffective, with its laissez-faire policy approach highlighted in a MAFF paper stating that industry should “determine how best to produce a high-quality product and that the role of government should be restricted to prescribing a standard for the product and to enforcing observance of that standard” (Flynn et al. 2005).

The mid-1990s was characterised by the production of several high-profile reports, which asked fundamental questions of food safety regulation in the UK. The Pennington Report (1997) investigated a deadly outbreak of *E. coli* in Scotland, while the incoming Labour administration had commissioned a report by Professor Phillip James looking at food safety regulation in the wake of the BSE crisis (Shaw 1997), as well as announcing a government inquiry into the BSE crisis (BSE Inquiry 2000). While the government inquiry argued that MAFF had not put the interests of agriculture ahead of the consumer, by arguing, “it was not MAFF’s policy to lean in favour of the agricultural producers to the detriment of the consumer”, it did admit that “Confidence in government pronouncements about risk was a further casualty of BSE”. By this point, however, the Labour government had already set plans in motion to carry through one of the main recommendations of the James Report. This would be the creation of a fully transparent arms-length government department that

would regulate food safety in the interests of the consumer – the Food Standards Agency. The then Prime Minister, Tony Blair, welcomed such a move by stating:

The public has the right to expect the very highest standards of food safety. Confidence in the safety of the food we eat has been severely undermined in recent years and I am determined to rebuild that trust. I thank Professor James for his detailed and considered report. It provides an excellent foundation upon which the Government can build. It confirms my belief that we will benefit from a powerful Food Standards Agency. We need to create a structure that is open and transparent, and which acts – and is seen to act – in the interests of consumers.

The Pennington Report was more narrowly focused, providing recommendations on how to reduce the likelihood of another *E. coli* incident from occurring. However, despite not proposing sweeping changes at a national level, like the James Report, it did concern itself with the enforcement practices of EHOs and business self-checking approaches signified by Hazard Analysis and Critical Control Points (HACCP). The recommendations tacitly endorsed the UK government's drive towards soft compliance, by ensuring food businesses were responsible for their own control systems, despite media and public sentiment that the UK government should be putting consumers first by holding industry further to account.

The evolution of food safety enforcement has been relatively slow and steady throughout the past century or so, with new food law showing incremental changes. Environmental health work has largely been carried out by local authorities, with the relatively recent exception of meat inspection². Even with the BSE crisis, and the ensuing James Report leading to the creation of the FSA, food business inspection at a local level has stayed relatively constant. Through the Food Standards Act 1999, which led to the FSA's creation, the FSA has been granted the power to monitor and audit local authorities. The FSA can "step in" and require a local authority to take corrective action, if the local authority is not

² In April 1995, the Meat Hygiene Service (MHS) was created as an executive agency of the Ministry for Agriculture, Food and Farming, before transferring to the FSA in April 2000. The MHS took responsibility for the enforcement of meat hygiene legislation from local authorities. The MHS ceased to be an executive agency in 2010, when it merged with the FSA to form a new operations group.

enforcing businesses as set out in UK food law. As an EU designated national competent authority, the FSA has provided a food law code of practice for local enforcement.

4.3.3 Professionalisation of the Environmental Health Officer

While the remit of “inspectors of nuisances”, and the EHOs that superseded them, expanded throughout the timeline described above, their generalist nature has remained constant. One explanation is that even though there have been a series of Acts that deal with the competencies of EHOs, the basic legal goals have remained more or less the same. For example, “not of the nature, substance and quality expected of the purchaser”, as set out in the 1872 Adulteration of Food and Drugs Act, has been preserved right the way through to the current Food Safety Act (1990).

Over the last hundred years or so, however, inspectors have become increasingly professionalised. In 1883, the Association of Public Sanitary Inspectors was founded, which represented and began training inspectors of nuisance, now known as sanitary inspectors. The Public Health Act 1891 required the inspectors to attain a certificate from the Sanitary Inspectors Examination Board, with a diploma introduced in 1942. In 1951, a new diploma was complemented by a new name for the inspectors, that of “public health inspectors”. The 1960s ushered in the modern nomenclature of environmental health, which was now a graduate profession. This enhanced status granted the Association of Public Sanitary Inspectors a Royal Charter in 1984, and it became the Chartered Institute of Environmental Health (CIEH). The CIEH continues to oversee the training and qualifications of EHOs to this day.

4.4 The evolution of German food safety law and enforcement

Germany has a very different history from the UK when it comes to ensuring the safety and supply of its food. In many ways, the autonomous states that now make up modern Germany have historically faced many of the same issues as the UK. However, the fragmented nature of Germany throughout the Holy Roman Empire, and its second and third Reich, created a series of specific challenges that the Germany of today still confronts.

As in the UK, the growth of German cities posed particular problems. As Loschelder (1987) argues, people were becoming “less able to provide for their own needs with production, trade, and consumption becoming more diverse and varied, it was felt that laws were needed to protect people against fraud and danger to their health”. Medieval sausage and beer laws indicated a concerted, albeit limited, attempt to tackling the problem of food quality throughout the disparate German states. Indeed, the criminal law basis for food regulation in medieval Germany was rather violently apparent from this time too:

Penalties for violation of the food laws were quite severe. In Nuremberg, a grain dealer who used fraudulent measures had both ears cut off. A baker, whose rolls did not have the prescribed weight, was dunked under water while imprisoned in an iron cage. Those who produced food products that endangered health were often required to consume their own food products until they died. (Loschelder 1987)

In the final years of the holy Roman Empire, criminal law continued to underpin food safety. In the 1771 Code of Criminal Law, consumer interests were protected as threats were posed to those who fraudulently sold altered or spoilt food with fines or imprisonment (Loschelder 1987). Indeed, this criminal law approach of fines or imprisonment has continued to be an important bedrock of German food law.

Criminal convictions, however, were deemed insufficient in tackling the problem, and German cities introduced a wave of administrative regulations to target certain areas of food quality and safety. Specific food businesses were targeted, “Bakers especially, but also butchers, brewers, fishmongers and vintners were controlled very strictly as they often adulterated their goods” (Teuteberg 1994). However, there was not much consistency across German towns and before the unification of Germany in 1871, following the Prussian victory over France, German food law was a hodgepodge of loosely tied local provisions focusing on food purity and adulteration.

As was the case in Victorian Britain, 19th century Germany experienced population booms in cities, increasing the demand for urban food processing and the innovations it brought.

Scientific developments and the industrialisation of the food chain meant the consumer was placed ever further away from the production and processing of food. The consequence was summed up by (Teuteberg 1994): “The growing distance between producer and consumer as well as the developments in organic chemistry, by constantly analysing new ingredients which could secretly be added to the food, increased the possibilities of food manipulation”.

In order to deal with the rise in adulteration and the new problems created by increased urbanisation, the newly unified German state created an Imperial Health Administration (*Kaiserliches Gesundheitsamt*) in 1876 to “realise a more centralised system of control for food and consumer goods and to take account of the rapid scientific developments of the period, especially in the area of food chemicals” (Dressel et al. 2006). Not long after its foundation, the first national law on food and commodities, *Nahrungsmittelgesetz* (NMG), was introduced in 1879. With these new developments, there was a boom in state-sponsored sampling and enforcement of controls. For example, by the turn of the century there were over 100 agencies related to food safety in Prussia alone (Dressel et al. 2006).

The 1879 Law was, however, limited in reach. Only the towns and cities with the capacity to implement controls had substantial freedom in implementing local competencies and practices (Hierholzer 2010). The law was also vague, both because legal definitions lacked much clarity and because it purposefully sought to protect against the constantly changing nature of the food chain. As Hierholzer (Clark et al. 2006) makes plain:

The possibility of amending administrative orders and various indefinite legal terms were included within the food act of 1879. The criteria for measuring the quality of food products were consciously left undefined. The law only very abstractly spoke about “adulteration” and “imitation”. It very generally and abstractly defined the incriminating circumstances and the applicable punishments and imposed a rough framework for food monitoring; the definition of criminal acts was however left to subsequent ordinances and to jurisdiction.

Despite the imprecise definitions of the 1879 law, it did permit the police to enter a food business and take samples for analysis, as well as allowing district authorities to establish

stations where the analysis could be conducted (Teuteberg 1985). However, the police did not have the expertise to deal with the increasingly technical problem of food adulteration, and local authorities were not the driving force behind establishing analytical stations. Instead, much of the drive came from the creation of several important public and scientific associations. These were created, at least in part, in response to the limited reach of the 1879 law.

4.4.1 The amateur food chemists

During the political debate that led to the 1879 law, Ernst Leistner posted an advertisement in a newspaper in Leipzig, calling for the population to mobilise “self-help” action against adulterated food. His opinion, widely shared, was that local authorities were doing little in the way of effectively controlling the food trade. Leistner’s advertisement led to the formation of the Association Against the Adulteration of Food (*Verein gene die Verfälschung der Lebensmittel*), which became the vanguard for other similar self-help organisations established throughout German cities. By 1878, 20 such associations existed. Their goal was to deal with the deficiencies of local governance and mediate during any controversy rising from accusations of adulteration and related misdemeanours. As Hierholzer (2006) argued, “The ultimate goal was said to be the protection of the population from fraud and health risks. As a reason for these actions they noted the inactivity of government agencies, especially at a local level”.

The associations set up testing laboratories to which members of the public could bring in food to be sampled, and disseminated information through publications. They also organised public lectures to educate the German population about food issues. However, the associations also reflected the political approach to accountability in emphasising the personal responsibility of the public for the safety of their own food:

There were warnings against exaggerated public expectations and statements that ultimately it was the consumers’ responsibility to protect themselves from attacks on their wealth and health. It was proclaimed that reforms of the law did not preclude

self-responsibility of the consumer. The consumers, it was argued, were certainly partly to blame for their own situation. (Hierholzer 2006)

That point of view is quite different from the one that is mandated by the European Commission's General Food Law (regulation 178/2002) today, which lays the responsibility for providing safe food squarely at the feet of food businesses.

Businesses found selling adulterated food were blacklisted by the associations, whilst other businesses voluntarily put themselves forward for association oversight to gain a competitive edge, taking advantage of the non-partisan nature associations were perceived to have. Local authorities also utilised the associations' testing laboratories. The passing of the 1879 food law did little to change the *status quo*, as government authorities weren't mandated to set up their own control stations, so they continued to use the associations' facilities. The police, ostensibly responsible for enforcing food regulations, left more complex investigations into adulterated food to the associations' laboratories, confining themselves to simpler investigations.

4.4.2 The professionalisation of food chemistry

Despite these self-help associations taking such a central role in food control so quickly, they began to disband within a few years of Leistner's proclamation. Fundamentally they were plagued by an issue that has challenged federal food regulation since, the inability to form a harmonised and unified approach across the many associations founded. Whether it was the amount of testing, the type of testing, or the punitive measures handed out (through the blacklisting of offending companies), there was little intra-association agreement. Furthermore, the German public, who the associations sought to represent, and who lent credibility to their operations, eventually became apathetic to the need for such associations. The large public support that was initially generated soon waned and the associations' membership was only made up of upper middle-class professionals, as was generally indicative of 19th century German associations.

However, the increasing professionalisation of food chemists led to the establishment of associations of nutritional chemistry, such as the Free Association of German Food Chemists (*Freie Vereinigung deutscher Nahrungsmittelchemiker*), from the 1880s onwards. These served to fill the gap left by the decline of the self-help associations:

[The] internal process of the diffusion of knowledge and the convergence of methods was closely connected to the popularisation of nutritional chemistry: through popular scientific publications and exhibits that presented scientific progress and illustrated the instruments and methodology of food monitoring, the discipline sought to present itself as a mediator of certitude in an often-times insecure and alienating industrialised world. (Hierholzer 2006)

To establish themselves as an undisputed source of expertise, the professional associations sought to harmonise approaches to sampling food and interpretation of results. They were aided by a high level of public support and by food businesses who wished to increase public trust by bringing themselves under the auspices of the food chemistry associations. The inconsistency of governmental enforcement, coupled with the very few specific areas that it sought to clearly regulate, led to the establishment of private regulations under the direction of food chemists. The adaptability of norms relating to methods of sampling and control of food gave the associations of nutritional chemistry an edge over administrative laws which were marred in indeterminacy and trying to deal with the ever-changing nature of the food supply. There was, therefore, what Hierholzer (2006) describes as a “division of labour” between the imperial government setting unified laws that sought to capture the rapidly evolving food market and the effectual implementation of administrative regulations by food chemists:

The state established an institutional framework and a legal basis for uniform monitoring of food through the food act and further special laws. The implementation and the semantic filling up of the act was however de facto carried out by the food chemists. In this manner, private and sovereign law-making was intertwined. (Hierholzer 2006)

This public-private partnership paved the way for the corporatist tradition that Germany continues to operate upon.

4.4.3 The role of the veterinary profession in inspection

One important distinction with the UK, is that whilst in the UK the veterinary profession carved out its own inspection regime, specifically related to the inspection of food of animal origin (e.g. at slaughterhouses, farms and border inspection posts), German vets became intertwined with the general inspection of food businesses, serving as expert guarantors of enforcement actions. In the UK, food hygiene inspections have solely been the domain of EHOs.

Towards the end of the 19th century in Germany, veterinary supervision of food of animal origin had developed in a similar way to the UK. Booming city populations had led to the establishment of many small slaughterhouses, mixed into residential areas, which posed a health hazard as effluent would pour onto the street, rot and congeal, leading to potential health hazards. As a result, shortly before German reunification in 1871, cities had imposed strict rules on slaughterhouses and the need for veterinary oversight (following a standard set by Prussia with its *gewerbefreiheit*). The 1879 law recognised the role of vets in supporting the sampling of food of animal origin, in the now unified Germany. With the German Länder beginning to take over responsibility for the sampling of foodstuffs from the self-help associations at the turn of the 20th century, both vets and food chemists found themselves at the heart of enforcement practices. Their expertise continues to underpin government offices responsible for the inspection of sampling of food premises (*Überwachungsamt*), as well as the offices that analyse the samples collected (*Untersuchungsamt*). The need for veterinary and food chemistry expertise also marked a decline in the police carrying out inspections. There was a gradual change at the turn of the 20th century, from food chemists and vets *supporting* police inspections of food businesses, to replacing police inspectors entirely. One notable exception to this rule was Baden-Württemberg, where specialist police officers were employed right up until the turn of the 21st century.

4.4.4 The Role of the Food Industry

With the professional food chemistry associations (and for a short time, public self-help associations) proving so effective in setting standards for application and enforcement of food controls, other powerful interest groups were emboldened. Industry sought to challenge the monopoly of food chemists by introducing their own set of standards. The most significant outcome of this was the publication of the German Food Book (*Deutsches Nahrungsmittelbuch*) by the Union of German Food Producers and Traders (*Bund Deutsche Nahrungsmittel-Fabrikanten und Händler*) in 1905. The goal here was similar to that of the food chemist associations: to provide information and guidance, as well as attempt to standardise monitoring practices. The Food Book also allowed for constant revisions and was not hampered in the same way that imperial regulations were, further emphasising the division of labour in the German food supply. Many industry associations enforced the controls of food adulterants and either showcased good practice or applied punitive measures to members who had fallen foul of their private regulations. The Association of German Chocolate producers, founded in 1876, was one such example, providing association badges for its members to publicly show that they had complied with strict private regulations. On the other hand, the association punished violators of their guidelines with warnings, fines and exclusion.

The plethora of associations, norms and private regulations inevitably led to increased pressure to standardise food control practices across the Reich. The Reich Health Council (*Reichsgesundheitsrat*), founded in 1911 and consisting of a panel of experts, set about trying to harmonise such practices throughout Germany. However, the food industry was reluctant to let go of its recently acquired influence and was fearful that government-led harmonisation would bring a halt to their own food quality norms and private food control practices. Consequently, industry sought to block any harmonising policies and so, by the beginning of the First World War, as Hierholzer (2006) argues, “there was still no solution for the conflict about the ideal model for regulation that had been smouldering for decades”.

The beginning of modern German food regulation was therefore marked with deep fragmentation. Not only was it difficult to harmonise food controls across the German states, powerful interest groups sought to seek the initiative from central government authority. The fragmentation and corporatist solutions that are prevalent today in Germany can be traced back to the same issues that were presented to the lawmakers who passed the unified food law in 1876.

4.4.5 German Food Safety Regulation in the Twentieth Century

Surprisingly, two World Wars and the Nazi regime did little to alter the unified food law or the standardisation of food controls. The wars naturally brought food security to the fore, and the debate over food quality and safety receded significantly. Consensus drawn between powerful interest groups allowed for some progress in setting government regulations that underpinned Germany's food control system, rather than the abstract and ill-defined regulations that first made up the NMG. In 1927, this led to a much more detailed food law (*Gesetz über den Verkehr mit Lebensmitteln und Bedarfsgegenständen*), amended in 1936, with clearer definitions and established standards for inspection of premises and the chemical analysis of food (Sewekow et al. 2010). Coupled with an enforcement directive in 1934, which further harmonised the application of food laws across German territories, the central German government was at last beginning to have a degree of influence across its disparate territories, 58 years after a unified law was introduced.

During the Second World War, at the heart of the Nazi regime's food regulation, was the *Reichsnährstand*, a central authority that controlled every aspect of the German food supply chain. This new organisation intended to showcase the Third Reich's autonomy, as Paul (2009) states, "the Reichsnährstand was intended on the one hand, to ensure autarky and on the other hand, it emphasised the importance of *Blut und Boden* ('blood and soil') in Nazi ideology by promoting domestic products, sometimes with an explicit military motivation". Paul argues that until the end of the Second World War, German food policy was centred around the economic value of autarky and political ideologies as exhibited by the Nazi regime.

However, events following the Second World War led to the institutional linking of the food supply to public health, as opposed to economic considerations that had come to the fore during the Nazi regime. Now with much of the agricultural land being in East Germany, West Germany pushed the need for strengthening agricultural production through a discourse of “keeping the nation healthy and strong”. This was of special importance as, in 1949, average consumption barely exceeded 1000 calories a day (Paul 2009). The need for a healthy population, Paul argues, may explain why food policy came to be under the purview of health, rather than agricultural, authorities. West Germany continued the evolution of the national laws as set out before the partition of the country, with the now 11 Länder responsible for food safety enforcement. East Germany, however, took a different course of action. Enforcement was organised nationally, with the state *kreishygia* inspectors dealing with food of non-animal origin (as well as commodities) and the state veterinary service dealing with food of animal origin (BVLK 2016).

At the same time, in West Germany, the next substantial change in the law arrived in 1975, when the Food and Consumer Goods Act (*Lebensmittel und Bedarfsgegenständegesetz – LMBG*) came into force. It further defined Länder responsibilities for food enforcement and increased the power of the state to intervene for the protection of the consumer, which included controlling food advertising for the first time (Teuteberg 1995, Müller et al. 2014). It also furthered developments made in a 1958 amendment to the 1927 food law by setting provisions for testing, and regulating, additives. However, it was the approach to consumer protection, and misleading consumers in particular that caused the greatest reverberations, as Loschelder (1987) makes clear:

The LMBG protects consumers against harm from dangerous products, and from being misled about those products. No health-endangering food may be produced, nor may it be offered or sold in commerce. This health-protecting function is relatively easy to carry out because the statute provides for especially rigorous enforcement, with harsh sanctions. The statute also protects consumers from being misled with respect to the identity, quality, and quantity of food products. This function of the statute is much harder to execute, given the great diversity in objects involved. Essential to this purpose is knowledge of what the average consumer ought

to expect from a particular label or a particular product, in the light of general trade usage.

The reasonable expectations of the consumer, and how attributes such as quality may affect the safety of food continues to be a source of friction in the German legal system to this day.

With regard to enforcement practices, the LMBG clearly stated the requirements and qualifications for inspectors of food businesses, which continued largely unchanged until the 20th century and the impact of EU harmonisation. Länder and district inspection offices were still reliant on the expert knowledge of vets and food chemists, but the relatively new taxonomy of *lebensmittelkontrolleur* (food inspectors), also allowed for the vocational training of inspectors who had a background in the food industry itself, the police, or who were in administrative roles linked to food control offices. The LMBG was the spur that prompted the establishment of the Federal Association of Food Inspectors (*Bundesverband der Lebensmittelkontrolleure* – BVLK) in 1978, which has contributed to the harmonising of enforcement activities and training throughout Germany, and has played a central role in developing federal hygiene legislation.

Following the reunification of Germany in 1989, the “new” Eastern Länder came under the jurisdiction of the LMBG. The LMBG provided the cornerstone of German food safety regulation until greater EU harmonisation at the turn of the 21st century, which required feed as well as food safety led to the LMBG losing its food safety provision to the German Food and Feed Code (*Lebensmittel und Futtermittelgesetzbuch* - LFGB), which came into force in 2005. The LFGB also takes into account the list of provisions that have been underpinned by the EU General Food Law, 178/2002. The LMBG is still enforced, but now only refers to the regulation of tobacco products.

The assertion that German food was, or more importantly was *expected to be* clean and healthy, continued into the new millennium (Paul 2009). Whilst the UK had spent the last decade of the 20th century marred in the controversies created by BSE, the German Minister, Karl-Heinz Funke, and the Minister of Health, Andrea Fischer, had stated that

Germany was BSE free. And why would there be any doubt? It did not bear thinking about that German cattle could be infected in such a way. It helps explain, therefore, with Germany's food system inextricably linked to ideas of health, why the first cases of BSE, confirmed in Schleswig-Holstein on 24 November 2000, had such a profound impact not only on the institutions that sought to control the nation's food supply, but on the ingrained idyll that German food equated to health and wellbeing. The reaction was both instantaneous and far-reaching. Funker and Fischer swiftly resigned, and a report by the Federal Audit Court (*Bundesrechnungshof*) was immediately commissioned and undertaken by the organisation's president, Hetta von Wedel. This report laid the path for the institutional rearrangement of the German food safety domain. Mirroring developments in the EU, risk assessment and risk management were institutionally cleaved, with a Federal Agency for Risk Assessment separate from a new Ministry for Consumer Protection, Nutrition and Agriculture (BMELV, now BMEL) and a Federal Office of Consumer Protection and Food Safety (BVL) emphasising the importance of the new safety regime and the consumers it served to protect.

However, what was most striking about the German reaction to the BSE crisis was the language and sentiment used. The German Chancellor at the time of the BSE crisis, Gerhard Schröder, declared an "end to agricultural factories" (Paul 2009). Renate Künast, the first minister of BMELV, spoke of an *Agrarwende*, an agricultural turn, to combat "the ills of an agricultural policy geared to mass production" (Nicholson-Lord 2001). This was not a denial of a German expectation of linking its food to good health, far from it. It was a denunciation of modern practices that had led Germany astray from its much-cherished food autarky built upon the back of local, small-scale farms, rather than the impersonal factory farming processes that were being blamed for the BSE outbreak.

The effect of the German reorganisation of food safety was not just felt on a federal level, it also had the outcome of shaping local enforcement competencies and practices. As Dressel et al. make clear, with such a reorganisation there was inevitably a certain amount of centralisation (Dressel et al. 2012). Even though the Länder kept their enforcement competencies, there was greater sharing of best practice and sharing of standards. The BVL oversaw greater coordination between Länder authorities with the formation of

committees, such as the National Consumer Protection Consortium (*Länderarbeitsgemeinschaft Verbraucherschutz – LAV*), which usually meets twice a year, and in the event of a crisis.

4.5 The rise of the EU food safety regime

However, as Commission President, I will also be very clear that I will not sacrifice Europe's safety, health, social and data protection standards or our cultural diversity on the altar of free trade. Notably, the safety of the food we eat and the protection of Europeans' personal data will be non-negotiable for me as Commission President.

Claude Juncker 2014

Any study of a European Union Member State's regulation of food safety must take account of the primary role of the EU itself, given that today nearly all Member States' legislation in the domain has been set at a European level. It is perhaps no surprise that the regulation of food, from both an economic and a health standpoint, is of great importance to the EU, given that it is the world's largest importer and exporter of food. However, whilst legislation has existed since the beginning of the EU to deal with the running of the internal market and the free movement of goods, specific food safety legislation is a much more modern addition. Indeed, there are claims that food safety law within the EU is little more than a decade old (Alemanno & Gabbi 2014). This section will present a condensed history of the role that food legislation played and how the combination of crises and a desire for a common marketplace have led to food safety becoming one of the most crucial aspects of the European Commission's remit.

4.5.1 Food safety in the European Economic Community

From the signing of the Treaty of Rome that ushered in the European Economic Community (EEC) in 1958, European food law was not primarily concerned with the protection of public health, but with facilitating the internal market, as the free movement of goods symbolised one of the core principles of this new economic union. Indeed, the Treaty of Rome brought with it no guidance for food regulation. However, food regulation fast became an issue for the EEC and its successor, the EU, as it sought to guarantee the free movement of goods. And, as in the UK and Germany, the EU food safety regime experienced fundamental change

at the turn of the 21st century, putting safe food at the core of its remit. A key narrative to explore here is what Bernd van der Meulen (2014) defines as the EU's drive to harmonise food law across its Member States, from vertical directives to horizontal directives. The difference between these two methods of directive indicate how the role of food law moved from primarily guaranteeing the freedom of goods, to ensuring the safety of EU consumers.

Although the EU food safety regime is highly centralised, with increasing focus on harmonising regulation across all of its Member States, this has only been a relatively recent development. Although the free movement of goods across all borders was discussed, and general agreement sought, during the early years of the EEC, Member States were still highly independent. The nascent area of European food law struggled to supersede national laws as each Member State “sought to protect its own markets and enterprises wherever and however possible, and to trust the judgments of its own institutions before those of the Union or other members” (van der Meulen 2014). However, in order to attain the goal of the free movement of goods, national standards had to be effectively harmonised.

The initial approach to harmonisation, which prevailed in the 1970s, was to introduce vertical legislation, defined here as ensuring agreement between Member States on the composition of specific food products. This “recipe-legislation” set highly specific requirements for certain foodstuffs, such as the levels of cocoa content a product is required to have before it can be called chocolate (see EC Directive 2000/36). The issue here soon became very clear: the sheer scale of setting compositional requirements for all foodstuffs traded throughout the Union simply proved impossible. Added to the fact that the Treaty of Rome required that each new piece of legislation had to be unanimously backed by the European Council, the EU soon jettisoned this approach to achieving market liberalisation across the Union.

4.5.2 The changing approach to food through the European Court of Justice

After the failure of vertical legislation, in 1985 the EEC decided to use labelling as a means of informing consumers about the differences in composition, and production methods, of foodstuffs (Leibovitch 2008). This had a knock-on effect, as through the principles of equivalence and mutual recognition, Member States had to allow the movement of food that had been produced to an equivalent standard of other Member States, even if there were compositional differences. Thus, EU food law increased in significance for Member States

with the European Court of Justice (ECJ) defining quantitative restrictions and equivalence, in part due to the outcome of the 1974 Dassonville case. Here, Mr Dassonville bought British-sourced Scotch Whiskey in France (as it was cheaper) and attempted to re-import it into Belgium. However, Belgian law required that all Scotch whiskey had a certificate of authentication from the relevant British authorities. As the whiskey was bought in France, such certification was not possible and therefore Mr Dassonville created his own certification and was duly charged with fraud by the Belgian authorities. The Belgians submitted questions of interpretation to the ECJ to determine whether such a charge of fraud was compatible with European Law. The EU Court of Justice rules “that all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra community trade are to be considered prohibited in the absence of a specific allowable justification.” These justifications are defined as being based upon the need to protect human, animal or plant health, which in this case the court had ruled had not been impeded. This ruling laid the foundations for Article 34 TFEU, which stated, “Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States”. This article of European Law has become essential for providing the free movement of goods, denying quantitative restrictions on the flow of goods between Member States unless due justification is given.

However, van der Meulen (2014) argues that the seminal ruling that helped bring about the development and dominance of European food Law, was the Cassis de Dijon ruling of 1979. The case was brought before the ECJ because a German supermarket chain, Rewe, attempted to import Cassis de Dijon from France. The German authorities barred this import as German product standards required such liqueurs to have at least 25% alcohol, whilst Cassis de Dijon only contained 20%. The authorities argued that a lower alcohol content could encourage binge drinking, and that consumer trust in the German law setting such requirements would be compromised. The European Court applied the rule of reason, stating that the German authorities’ arguments needed to meet an urgent need. However, the Court did not see either of the German authorities’ objections as satisfying the rule of reason, stating that the import did not provide a public health concern and the German market already had a range of alcoholic beverages on sale that had an alcoholic content of less than 25%. The combination of the Dassonville ruling and the Cassis ruling meant that EU law was now superseding national legislation, as the principle of mutual recognition stated that products lawfully produced and sold in one Member State could not be barred from other Member States on the

grounds of national legislation. This allowed for the full implementation of an internal free market as national standards were subsumed under EU legislation. The EU had implemented a system of negative harmonisation, where products were legal irrespective of which national standards they acquiesced to.

The implications for national Member State laws were great, as the supremacy of EU law took hold. For example, the German Reinheitsgebot, a purity law from 1516 determining the ingredients permitted under German standards, fell afoul of the principle of mutual recognition, as importers of beers that had additives in them (which were banned under the Reinheitsgebot) found that they could now import their beer into Germany, and in some cases, bring legal action against the German State for losses incurred due to the quantitative restriction created by the purity law.

Although the Dassonville and Cassis de Dijon rulings were important for establishing the internal market, they led to a fundamental issue, potentially incentivising the production of foodstuffs in Member States with laxer national standards and forcing countries with stricter or more developed standards to accept these products under mutual recognition. Issues with harmonisation were brought back to the fore, this time focusing on Member State national standards, rather than product specific legislation. As van der Meulen (2014) summarised, “Before Cassis, harmonisation was seen merely as a condition for the functioning of the internal market. Afterwards, emphasis shifted to the need to alleviate the consequences of the internal market”. There was a shift from product specific vertical directives, to horizontal directives, which sought to cover large groups of foodstuffs by covering aspects that a range of products might have in common. By doing this, the EU was bringing a much larger proportion of the food chain, across its Member States, under its supervision.

4.5.3 The BSE crisis and institutional change

Although the principle of mutual recognition was now being applied to quantitative restrictions between Member States, the key driver for facilitating such changes was still the facilitation of the Common Market. Food safety could be used as grounds for a Member State to place quantitative restrictions on the products of another, should they have demonstrable implications for public health, but economic forces still dictated the movement of goods. This was to change quite abruptly with the advent of the BSE crisis. As was the case with the UK

and Germany, the EU was rocked by the claims and counter-claims made about the disease, its fatal impact across several Member States, and the extreme levels of cattle slaughter as countries tried to quell further outbreaks. The BSE crisis “Caused an earthquake in the legal and regulatory landscape of Europe” (van der Meulen 2014) that led to food safety unquestionably becoming the central driver of the EU’s food chain.

In the wake of the BSE crisis, the European Parliament commissioned an enquiry to look into how the crisis was handled (European Parliament 1997). The 1997 report was critical of the European Commission’s response to the crisis, citing that industry interests had been put ahead of public health, the scientific evidence that underpinned their action was not robust enough, and there had been a lack of transparency. In short, the EU’s response was insufficient and its institutional obligations to consumer protection were found especially wanting. The response was swift and further increased the European Commission’s power over EU food law. The Directorate General Consumer Policy was replaced by the Directorate General Health and Consumer Affairs (DG SANCO). A scientific Steering Committee was established in DG SANCO to ensure that decisions were underpinned by a scientific evidence base, while DG SANCO also took primary responsibility for food legislation from DG Agriculture. In 1997, the Food and Veterinary Office (FVO) was also established, whose primary objective was to monitor food control systems across the EU, as well as third countries looking to import into the EU. The economic considerations of agriculture and the broader food trade had been publicly trumped by issues of consumer protection and health.

In further response, the European Commission published a short Green Paper on the general principles of food law in the EU, and argued that there needed to be better control measures from the Commission itself. Fundamentally, the green paper argued that a central text of European food law needed to be established, rather than relying on previous rulings such as *Dassonville* or *Cassis de Dijon* (EC 1997):

For many foodstuffs of agricultural origin common quality standards have been laid down. However, European food law has developed piecemeal over time. Consequently, there is no central unifying text setting out the fundamental principles of food law and clearly defining the obligations of those concerned.

The need for this central text of European law, and associated guiding principles, led to the Commission's White Paper on food safety in 1999, which delivered the most significant changes regarding the regulation of food safety. The opening sentences of the white paper make clear the important role that food safety would now play (EC 1999):

Assuring that the EU has the highest standards of food safety is a key policy priority for the Commission. This White Paper reflects this priority. A radical new approach is proposed. This process is driven by the need to guarantee a high level of food safety.

Thus, food safety was no longer subsumed under the machinations of the market. It was not even seen as one of many considerations in the running of the single market. Rather, food safety was now “key”, a “radical new approach” was proposed and there was a “need to *guarantee* a high level of food safety” (emphasis added). Food safety became the top priority – it needed to be guaranteed. At the centrepiece of the EC's radical overhaul of food regulation was the establishment of an independent risk assessment body, the European Food Safety Authority (EFSA), established in Parma in 2002. According to the White Paper, the principal responsibilities for EFSA would include a “number of key tasks embracing independent scientific advice on all aspects relating to food safety, operation of rapid alert systems, communication and dialogue with consumers on food safety and health issues as well as networking with national agencies and scientific bodies”. EFSA would ensure that the commission would be provided with the best available scientific evidence for their decision-making process, one of the key criticisms of its approach to the BSE crisis. It should also be noted that the consumer now plays a central role in EFSA's remit, signalling an end to the European food trade being dictated by the food businesses that drive market forces, and instead putting consumer interests at the heart of regulation.

4.5.4 The General Food Law

In addition to the institutional change, the legal framework that supported food legislation was also rewritten. Indeed, many point to this moment as the EU's first specific food safety chapter, as opposed to the wider field of food regulation, driven predominantly by economic factors. Not only did the introduction of EC 178/2002 (the EU General Food Law – GFL) lay down the foundations for the creation of EFSA, it also introduced a set of principles that

direct EU action with regard to food safety to this day. These principals are the Risk Analysis Principal, the Precautionary Principle, and Transparency. At first glance, all of these principles look entirely suited to dealing with the issues that plagued the Commission and Member State regulators during the BSE crisis. On the face of it, transparency was aimed at ensuring that consumers could scrutinise decision-making, risk analysis would allow for all decisions to be made on a designated framework of science-based evidence, while the Precautionary Principle would ensure that in the event of scientific uncertainty, a “better safe than sorry” approach could be adopted to regulating potential hazards. The Commission produced a White Paper on the Precautionary Principle barely a month after the White Paper on food safety, and heavily referenced the earlier Green Paper on food safety to indicate the need for the formal implementation of the precautionary principle into EU regulation.

The General Food Law was not the only major development of European food law. As part of the commission’s approach to increasing harmonisations levels across its Member States, regulation 853/2004, entitled “on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules”, was introduced. This regulation is all-encompassing in nature as it sets requirements for the control of food and feed across the food safety policy domain. Its scope, in ensuring the effective implementation of official controls for food and feed, covers a wide range of activities, as Article 1 makes clear:

The official controls should be carried out using appropriate techniques developed for that purpose, including routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples.

As such, the reduction and elimination of risk is central to the remit and scope of the regulation. Under Article 1 of the regulation, the scope is defined as follow (emphasis added):

1. This Regulation lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at:

*(a) **preventing, eliminating or reducing to acceptable levels risks** to humans and animals, either directly or through the environment; and*

(b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.

Thus, in the space of a few years of the European Parliament's Inquiry into the BSE crisis, the legal and institutional landscape of European food safety had completely changed. Safety had become the watch word for the food trade, and the Commission had sought to implement a range of principles to ensure that remained the case. The Commission's increased influence in the running of Member State food safety regimes had led to a great deal of harmonisation, with regulations such as 882/2004 replacing piecemeal directives of the past. The Commission, through the GFL, had emphasised the need for all food sold on the market to be safe, underpinned by a robust approach to risk.

4.6 Conclusion

Tracing the development of food safety regulation across Germany and the UK emphasises some key similarities and differences that may have an impact on the application of risk-based regulation on the EU Member States. While both the UK and Germany share the same starting point for food safety regulation as 19th Century industrialising societies whose opening of global trade in foodstuffs led to an increasing focus on food fraud, there have been key differences in the ensuing century or so. Specifically, there are three main factors that may explain policy divergence within the current harmonised system of EU food safety regulation: the role of professional interest groups; the linking of health concerns to food; and the level of regulatory fragmentation.

The role of interest groups within the German context underlies the Bismarkian corporatist traditions that dominate many German policy domains. The role of self-help public organisations at the end of the 19th Century, giving way to a string of national regulations underpinned by Länder governments, food businesses, the entrenched veterinary profession and the developing food chemist- and later food inspector- professions. This is apparent today, with food safety inspection not the purview of a single profession, instead supported by an array of state and non-state rules and associations. The UK could not be more different, with the development of generalist environmental health officers taking a central role³, who had succeeded their Victorian counterparts, the inspectors of public nuisances. The UK has

³ While the veterinary profession played an important part in the UK trade in food of animal origin, it did not have such an integral influence across enforcement practices in food safety, unlike Germany.

never seen the involvement of non-state actors in the regulatory landscape to the extent of Germany's public self-help organisations and industrial standards. As such, in assessing the implementation of risk-based approaches within the two countries, one might expect a more varied picture within the German context, due to the greater diversity of interest groups involved in the enforcement of food safety standards.

With regard to the linking of health concerns to food, both countries implemented legislation in the 19th Century that sought to protect public health, albeit from a food adulteration, rather than hygiene, perspective. However, following the Second World War, there was a marked difference in the prioritisation of public health within the two countries. In the UK, public health played a relatively minor role in comparison to the promotion of agriculture, with accusations of imbalance plaguing MAFF until it was dissolved in 2002. In contrast, notably within a West Germany that had been cleaved from the agricultural heartlands of East Germany, food shortages led to food policy being institutionally linked to health ministries, as opposed to agricultural ones. While a string of food safety incidents in the 1980s and 1990s within the UK led to health taking a more prominent role, public health had been ingrained within Germany for much longer. This can be seen by the reaction to the BSE crisis within Germany, both in the shock that such a public health epidemic could develop and in the sweeping language used within the subsequent agricultural turn – language that was more fundamental than in the UK context. Due to the long-standing association to public health in food safety, it might be assumed that precautionary approaches may play a greater role in Germany as opposed to the UK, to the detriment of risk-based approaches.

The organisation of food safety enforcement within both countries may be another important factor in understanding differences to risk-based approaches. Food enforcement matters within Germany have historically been devolved to its constituent Länder, reflecting the myriad states that came together to form modern day Germany. Matters were further complicated by the division of West and East Germany, with East Germany implementing a centralised enforcement regime until reunification with the West brought it back under individual Länder responsibility. Conversely, the modern history of UK food safety enforcement has been one of much greater central government control, with government departments setting expectations for local enforcement and providing oversight. Fragmentation within the German context may well test the limits of risk-based approaches being universal, than in the centralised UK system.

Finally, it is important to bear in mind the importance of the development of food safety regulation within the EU, and how ideas of risk have translated to Member States from the standard setting regime of EU institutions. While early developments within the European Economic Community was predominantly focused on trade and later harmonising the application of standards across Member States to underpin the free movement of goods, high profile food safety incidents at the turn of the century shifted the EU regime to focus primarily on health (in many ways reflecting the shift to health within the UK). Since this radical change in regime, there has been an increasing interest in implementing risk-based approaches. With the primary goal of food safety so explicitly outlined within the current General Food Law, how are risk-based approaches intended to help underpin this? The answer to this question lies in the approaches and language of risk that the EU food safety regime utilises within standard setting, and will have consequences for how risk-based approaches will be implemented within the UK and Germany.

Chapter 5: Food Risk and the EU

5.1 Risk and hazard in the EU food safety domain

The EU regulation of food safety entails a highly complex array of social, cultural, economic and legal issues throughout the regulatory pathway. At a macro level, international agreement is essential to the fair trade of safe food. At a micro level, there is a need for the consistent application of enforcement protocols to ensure that food risks are highlighted and mitigated. To achieve this, the European Commission makes clear that risk-based approaches are critical to maintaining a high level of protection, promulgating risk analysis as a core principle of the EU's General Food Law regulation 178/2002 (GFL). As the Commission states in the GFL, "The Union has been at the forefront of the development of risk analysis principles and their subsequent international acceptance." At the same time, article 14 of the GFL states that "Food shall not be placed on the market if it is unsafe" (see fig. 3); suggestive of a binary safe/unsafe conceptual dichotomy that could be in tension with more nuanced approaches to risk acceptance. As Member State food laws are so harmonised with European law, the ways in which the Commission and its subordinate bodies interpret ideas of risk and its application, could have important ramifications for Member States. So how does the Commission's apparent appetite for risk square with the GFL's insistence that all food placed on the market must be safe?

Nowhere is the tension between hazard and risk more apparent than with food import controls. One of the key foundations of the EU is the free movement of goods, as originally laid down in the Treaty of Rome, which has required the harmonisation of food laws across Member States to ensure that food produced in one Member State can be sold in another. The rationale for harmonisation is clear; if Member States had different yardsticks to measure food safety and quality and to justify import controls or bans, the free movement of goods could be undermined. "Risk" ideas have been central to ensuring the consistent application of controls across the EU; not least in requiring more stringent levels of checks for "high-risk" than "low-risk" products. However, as this chapter will show, the EU's classifications of "high" and "low" risk products have historically been relatively crudely drawn according to whether products are of animal or non-animal origin respectively. On the face of it, such a classification looks far more "hazard-based" than "risk-based", since some food of animal

origin, such as a tin of sardines produced to the highest production standards, is likely to be far safer than raw salad ingredients contaminated with *E. coli*. Given the Commission's promotion of risk-based enforcement strategies, that puzzle raises the question of the extent to which the EU's food import regime reflects a risk-based approach in practice, and if not, why not.

To answer the questions posed above, the author interviewed policymakers from the primary European institutions tasked with dealing with food safety, namely DG SANTE, EFSA and the FVO, to determine the appetite for risk at a European level. Interviews were also conducted with officials from national and local competent authorities as well as with officials applying and enforcing food import controls at ports of entry to the UK and Germany, at least insofar as it was possible to secure access. As will be discussed below, those interviews reveal the EU's risk appetite and the tensions at play between hazard and risk within the import regime. First, however, this chapter considers some of the fundamental tensions between risk, hazard and safety that are present in the EU's General Food Law.

Food safety requirements

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.
3. In determining whether any food is unsafe, regard shall be had:
 - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
 - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.
4. In determining whether any food is injurious to health, regard shall be had:
 - (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
 - (b) to the probable cumulative toxic effects;
 - (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.
5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.
8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.
9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

5. 2 Acceptability of risk in the EU

5.2.1 Setting acceptable levels of risk

As the GFL states that all food placed on the market must not be “unsafe”, we are immediately hit with problems of defining what “safety” in the EU context means. Meulen and Szajkowska (van der Meulen & Szajkowska 2014) warn that simply discounting all the practices and products that make up the EU’s classification of unsafe food, does not leave us with a definition of safe food. What these authors do suggest is that the definition of food safety provided by the Codex Alimentarius – an “assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use” (Codex 1999) – would not be understood differently in EU food law and can be used as a working definition. However, both the GFL’s demand that food should not be unsafe and the Codex’s definition explicitly stating that no harm should come to the consumer could be interpreted as zero tolerance of risk. The general objectives of the GFL do not talk in such absolutist terms, stating a need to “guarantee a high level of protection of human life and health and the protection of consumers’ interests” (178/2002). This, the Commission would no doubt argue, allows for the tools of risk analysis, as defined in Chapter 4, to help underpin what exactly a high level of protection should look like. But couldn’t a high level of protection still lend itself to a more hazard-based approach of safe/unsafe, and render many of the tools of risk analysis largely redundant?

To address that question, we need to consider what the EU defines as a high level of protection and whether that definition creates a conflict between guaranteeing the safety of food and the risk-based approaches that are purported to underpin it. Defining what a high level of protection looks like, however, is a key difficulty facing EU regulators as they try to ensure a food safety system that is both accepted and feasible to implement across 28 different Member States. As one official in DG SANTE explained:

To say what is the lowest level of risk which is the border of negligence, in that below [that level] we don’t care, there it is very difficult. Everybody knows that if you have a toxic substance with high concentration in food, that is something you need to sort out. But when you are at the other end [with low concentrations] where maybe in some very specific conditions, some people may have some unease, should you look

on that or not? Where is the border? And what is difficult in the food safety area is that this is an issue for every citizen of the European Union. (DG SANTE_2014d)

This statement suggests that there is considerable uncertainty surrounding the statement that all food should be safe. Does the statement hold as true for the Dutch as it does the Italians? Or does the statement hold true for vulnerable groups in society who may be more predisposed to certain risks inherent in food? Trying to set acceptable levels that consider a wealth of variation in different Member States can prove futile, with a respondent from EFSA using animal welfare issues as a case in point:

We have very little border conflicts when it comes to animal welfare, where there could be. In the risk analysis framework, one thing that you do is define the acceptable level of risk and appropriate level of protection. And when we assess welfare of animals, comparing different ways of doing different things, we end up ranking them, but it's very difficult for the manager to come with a real figure for what is acceptable and what is not acceptable. (EFSA_2014f)

This example suggests that there has been a large degree of reticence to setting the acceptable level, for fear of sparking issues across Member State borders. On a fundamental level, the Commission appears to face problems in setting the acceptable level of risk regarding public health:

Politically speaking, where is the acceptable number of healthy people? How do you set priorities? We are discussing this every year. We have to cut down the overall resources because of the overall economic and political situation, so that we have positive and negative priorities. (DG SANTE_2014d)

By positive priorities, these are the ones that DG SANTE prioritises, such as endocrine disruptors in food packaging materials, pesticide residue levels in food, and updating EU regulations on official controls (882/2204). However, the negative priorities are more revealing about the range of food safety concerns that cannot be easily addressed, due to concern for European solidarity:

And then you have negative priorities. Let's say two people die somewhere in East Europe. Can you say, "sorry guys, we didn't look into that because it was a negative priority." It's politically impossible. (DG SANTE_2014d)

This conundrum indicates the tension between the technical determination of priorities and the ways in which such prioritisation will be perceived by the public. But it also suggests that the explicit demand that food placed on the market should not be unsafe, makes it hard to adopt a proportionate risk-based approach to prioritisation, especially if one's negative prioritisation leads to deleterious consequences. Conversely, it could be argued that by clearly stating the risk-based decision-making behind such negative prioritisation, risk becomes a shield for the regulator as it can argue that it prioritised the hazards that posed the greatest potential risk. However, at the EU level, this is still problematic due to the self-avowed goal of ensuring safe food on the market.

5.2.2 Institutional risk

It would be wrong to assume that there is agreement within the EU that talk of risk is reserved purely for the sphere of societal risks, in this case food safety risks to consumers. Rather, it could be argued that the "rules of engagement" for the discussion of risk have not been clearly delineated, as a respondent from the UK Foreign and Commonwealth Office made clear:

What are we talking about in terms of risk? Is it food safety risk to consumers? Is it risk of non-compliance, which may intersect with risk to consumers, or may not? Is it risk to the employment of enforcement officials, with a vested interest? Is it risk of a market being flooded with competitive products that may disadvantage national farmers? That's why everyone is talking about risk but it's never defined absolutely that we're talking about a food safety risk to consumers, which is probably where we should be. (FCO_2014)

The ubiquitous nature of risk, a concept that Chapters 1 and 2 argued is still ill-defined, makes having a shared understanding of risk difficult, especially in a supranational context such as the EU. The above quotation also offers a useful insight into describing how institutional risks might shape the EU's risk appetite and approach to societal risks. For

example, the GFL's insistence that no unsafe food should be placed on the market reflects a broad European risk appetite in relation to food. Across EU institutions dealing with food safety, there was a general feeling that Europeans are very conservative when it comes to food, reflecting a very low appetite for risk. Public views are, of course, somewhat tempered by historical and contemporary sociocultural practices that vary between different Member States and would affect risk perceptions. However, there was a determination at Commission level that such a high profile and damaging incident such as the BSE crisis should never happen again. But this was not purely for the societal public health impacts that the BSE crisis had. It was for the reputational damage to both Member States and the European Union and the risks to the beef market that led to the creation of an explicit GFL with a clear emphasis on guaranteeing food safety. As one respondent in the FVO commented, the Commission didn't just take measures to ensure the safety of beef on the market that went beyond what was scientifically needed, but took measures that would put any issues of safety beyond any reasonable doubt:

Look at BSE, what that has cost, and ultimately, the vast majority of the measures we took in relation to BSE. The problem was not so much safety; the problem was regaining consumer confidence. From a pure public health perspective... if you want to ensure that beef is safe to the consumer, all you need do is remove the specified risk material... scientifically it's safe. So why then do we bother with the ban on meat in bone meal, the mandatory testing of all healthy bovines at 30 months? It was basically to restore consumer confidence. It wasn't enough to say beef is now safe, we have very strict measures in place to remove the specified risk material. Consumers had already made their minds up; they weren't buying beef anymore. Beef consumption had collapsed by 50% plus in Europe. So, it gets back to the firebreak, you have to go further than might scientifically even be considered necessary to re-establish confidence. This is not a lab experiment... you're dealing with subjective opinion... and occasionally you're going to have to go to extraordinary lengths to restore confidence. (FVO_2013a)

The need to restore public confidence is the central imperative here. That there needed to be a “firebreak” and “extraordinary lengths” helps illustrate why the Commission, in the aftermath of the BSE crisis, needed to send out a clear message to reassure consumers worried about the safety of their food. Dealing with consumer perceptions has led to some frustration, as the

way in which food industry and the regulator are viewed can sometimes mask the efficacy of the food safety regime overall. As an official at EFSA put it:

Something being safe is pro-industry and something not being safe is consumer protection. [If something's deemed safe] It's not affirmation that the system works, it's pro-industry. That's how it's perceived. And yet if we come out with a warning that something needs to be improved, it's not "how did the system ever get to this stage", instead it's "finally someone has a tripwire under industry, and good on EFSA for standing up for us". (EFSA_2014a)

The idea presented here that communicating an aspect of a food business' procedure or product as safe is met with suspicion that the regulator is in the pocket of industry, shows the delicate situation that regulators find themselves in with regard to consumer confidence. And fourteen years after the GFL was published, regulators at an EU level are still deeply concerned about the effect that a large-scale food safety incident could have on consumer confidence. In this sense, the EU food safety regime has to constantly manage its own institutional risks as much as the societal risks that are posed to consumers. An EFSA official stated this constant challenge by saying "Anything related to food resets everything, because food is central to people's lives." (EFSA_2014f) By "resets everything" it was meant that food safety incidents could have the potential for deep-set institutional reform within the organisations that serve the policy domain.

5.2.3 Unresolved tensions between hazard and risk

Fundamentally, consumers don't expect the food they buy to be unsafe. As the EFSA official put it: "We assume that food is safe, that it's a given. People don't think about anything harmful when they go to the supermarket" (EFSA_2014f). So, when things do go wrong, the resulting shock and anger is even more palpable. But does this consumer assumption that food is safe indicate that the GFL has been successful, as the EU has had a period relatively free of food safety scandals since the BSE crisis, and subsequently focus has shifted elsewhere? The EFSA official quoted above did feel that the public eye has shifted away from the issue of food safety:

Right after the second world war, people were worried about food security, then came the food safety issue. Now we're not worried about the security or safety, it's now the acceptability of the food. So it's about GM, it's about carbon footprints, it's about animal welfare for what is acceptable. We're still working on safety, while maybe society has moved on and regards it as a given. (EFSA_2014f)

This is not to say that those interviewed in EU institutions felt that food safety was not important, far from it. Most respondents felt that the fact that food safety was not seen as a going concern indicated how well the EU food safety regime was functioning but that the principles set out in the GFL are still relevant today. The regulation of food safety is a duty that requires a suitably robust regime to be able to ensure it. As an FVO official argued:

Food safety is essentially seen as a public good. And in many respects so it should be. I think it's a quid pro quo for the integrated food markets that we have. You can't have it both ways as a regulator, standing over a system that allows trade to take place on a massive scale, but when it comes to the safety [say to industry], "look after it yourself, don't hold us responsible". (FVO_2013a)

The above comment indicates a regulatory commitment to ensuring the safety of all food placed on the market, rather than passing responsibility to industry and leaving the regulator purely in the role of an auditor. That commitment, however, lends itself to a regulatory perspective on food safety that focuses on food safety hazards rather than risks. The reason is that that perspective directs regulators' attention to the range of potential food safety harms that might arise irrespective of business behaviour – i.e. hazard – rather than the likelihood of those harms occurring, which is dependent on business compliance with regulatory demands – i.e. risk. In other words, regulators are driven to actively seek out food safety hazards, rather than retreat to measuring business compliance as a proxy of food safety.

Even with the European Commission making overtures to risk-based policymaking, there are those who think it is simply not possible. The delegation of power within the EU framework provides an added hurdle to implementing risk-based approaches beyond individual Member States:

The discussion of risk is much the same at national or EU level, but at the EU it's much harder to get what I would class as a genuine risk-based system agreed, as there is a generally precautionary stance from many officials involved both in field operations, Member State policy and European Commission policy. And that's also reflected in the very hazard-based approach taken by many MEPs. Post Lisbon the parliament is having a much greater effect when they're having input into legislative instruments. (FCO_2014)

The risk averse nature of politicians is nothing new; what elected officials want risks to impact on their watch? But the point of the FCO official's concern is that with each layer of governance, from street level bureaucrat to Commission official, further blocks to risk-based regulatory approaches are introduced. Thus, the Lisbon Treaty's empowerment of the European Parliament added the vote of MEPs as a powerful veto point in addition to the difficult task of balancing the interests of 28 different Member States.

That is not to say that there hasn't been a push for more risk-based approaches amongst Member States, for example through the use of soft compliance and earned recognition for industry, as Chapters 6 and 7 will discuss. But the quotations in this section perhaps suggest that any hazard/risk tensions present in the GFLs commitment to safe food and risk analysis have not needed to be addressed, as public focus has shifted away from issues of food safety. Perhaps the relatively calm EU food safety regime brought about by the GFL has led to the Commission applying the old English adage, "if it ain't broke, don't fix it".

This section has shown the difficulties of being overtly risk-based as a starting point for EU-wide regulation, as setting acceptable levels of risk across Member States brings with it institutional risks for the EU food safety regime infrastructure. There still appears to be a large degree of sensitivity to public perception within the EU apparatus, considering the sweeping changes that the BSE crisis brought about. This might help explain why, despite the EU's insistence on risk-based approaches, there are conflicting approaches to ideas of hazard and risk within the GFL.

As stated in the introduction, food import controls offer an interesting case study as to whether the hazard/risk tensions discussed in this section manifest themselves in enforcement activities that are closely controlled through EU oversight. In the next section, I will provide

the historical precedent for EU food import controls, and then discuss whether current regulations and directives are overtly risk-based or hazard-based in their outlook.

5.3 The case of food imports

5.3.1 A brief history of the EU infrastructure behind food imports

The history of EU food import regulation mirrors the staccato approach to harmonisation and integration that has characterised EU approaches to regulating food safety as outlined in Chapter 4. Such development has been largely predicated on trade concerns and the establishment of the single market (the functional successor to the EEC's common market). It was clear that by the 1980s, the common market idyll that underpinned the creation of the EEC had not been realised. While a customs union between Member States was intended to facilitate the movement of goods and services, it was severely hampered by differing national standards and protectionist stances. The EEC Commission, under the stewardship of Jacques Delors, attempted to rectify this, seeing a common market as a remedy to the then international economic malaise. This drive led to the publication of a White Paper in 1985, entitled *Completing the Internal Market*, which sought the removal of physical, technical and fiscal barriers to the movement of people, goods and services across the community by combining positive and negative integration (see fig 5). The Cassis de Dijon and Dassonville cases described in Chapter 4 were examples of negative integration, as they corrected and regulated against discriminatory practices by Member States that impinged free trade. Positive integration was achieved through clearer definitions of the Commission's role, as articulated in the Single European Act (SEA), which was a direct result of the 1985 White Paper. The SEA was the first major regulatory revision of the EEC since the Treaty of Rome, and gave a deadline of 31 December 1992 for the EEC to establish a single market. Delors articulated the extent of the treaty by stating:

The Single Act means, in a few words, the commitment of implementing simultaneously the great market without frontiers, more economic and social cohesion, a European research and technology policy, the strengthening of the European Monetary System, the beginning of a European social area and significant actions in environment. (EEC 1986)

To achieve such ambitious changes, the SEA laid the foundations for the strengthening of the Commission's hand in the legislative process that supported the creation of the single market. Central to this was an addition of a provision to Article 145 of the EEC Treaty, which read in part, "confer on the Commission, in the acts which the Council adopts, powers for the implementation of the rules which the Council lays down" (EEC 1987).

Positive integration: the adjustment of existing and the establishment of new policies and institutions endowed with coercive powers

Negative integration: removal of discriminatory and restrictive institutions and the introduction of freedom for economic transactions

Figure 4. Definitions of positive and negative integration (Tinbergen 1954)

Focusing greater regulatory power at the centre of the EEC was not universally popular, with British Prime Minister Margaret Thatcher vehemently arguing, "To try to suppress nationhood and concentrate power at the centre of a European conglomerate would be highly damaging". However, the fall of the Berlin Wall in 1989, and the reunification of Germany in 1990, drastically changed the political and economic landscape of Europe. With French and British concerns over an emergent Germany, further integration offered a way of tying Germany to the European project.

5.3.2 Discrepancy between Products of Animal Origin (POAO) and FNAO (Food of Non-Animal Origin) at import

The single market was established at the beginning of 1993, and was a central pillar of the European Union, which was formally established by the Maastricht Treaty in 1992. Of the three pillars of the EU, laid down by the Maastricht Treaty, "Union policies and internal actions" ratified the free movement of goods as stipulated in the SEA⁴. The harmonising effect of the creation of the single market was quickly apparent, with the introduction of Commission decision 94/360/EC, which stipulated controls that needed to be carried out at EU BIPs, and percentage physical checks that needed to be carried out at designated points of

⁴ The other two pillars were "Principles", which provided the legal basis for the Maastricht Treaty, and "Non-discrimination and citizenship of the Union", which bars discrimination on the basis of numerous factors such as gender, religion or ethnic origin.

import on POAO. The legislation also indicated that even towards the turn of the 21st century, the control of POAO at import was a much greater priority than FNAO.

If the EU has largely succeeded in ensuring harmonised action across its BIPs, has it also succeeded in implementing a risk-based system of control that guarantees the safety of food imported? The answer appears to be different dependent on what category of food import is being discussed: products of animal origin or food of non-animal origin. Risk terminology reflects the historical emphasis of prioritising the control of meat, with all imports of POAO categorised as being “high-risk”, unlike FNAO where only a small list of products from specific countries is deemed high-risk. The definition of high-risk products given to port health authorities is, “feed or food that is either a known, or an emerging risk to public health. This may be due to the presence of pathogens, toxins and contaminants.” (FSA 2013) For FNAO placed in the high-risk list in 669/2009, one could argue that such a definition makes sense. Because there is a degree of specificity in the country of origin, the batch number (in as far as they target specific subclasses of a food product) and an articulation of the hazard that has explained the product’s place on the list, such logic would explain the need for increased controls at import. Furthermore, the list of products 669/2009 is reviewed by the Commission on a quarterly basis, and any updates to the list are informed by a range of data from a variety of sources (FSA 2013):

The approach is evidence based using a number of information sources. These include data from the Rapid Alert System for Food and Feed (RASFF); reports from the Commission’s Food and Veterinary Office on feed and food safety procedures in non-EU countries; reports and information received from non-EU countries and the European Food Safety Authority, scientific assessments. All of these sources are taken into account when the European Commission reviews the list to develop proposals to present to the Member States for their consideration.

However, fundamentally there is no such delicacy in assessment when it comes to the risk determination of POAO, as it is all determined to be high-risk.

For “high-risk” foods, controls at import include documentary checks, such as public and/or animal health certificates, commercial documentation and crucially a Common Veterinary Entry Document (CVED), which serves as a pre-notification from the importer and shows the

outcome of all checks against the product it is verifying. Identity checks are also required to ensure that the imported product and any health marks and stamps or related product/packaging information matches the accompanying documents. Finally, physical checks are required in the form of testing and sampling a percentage of products imported (as specified in Commission Decision 94/360/EC for POAO, see table 1).

The regime for controls at import for food of non-animal origin has historically been markedly different insofar as there has never been any requirement to carry out full documentary or identity checks on FNAO consignments coming into port, irrespective of any risks posed by the food. However, the regime has started to change in recent years. EU Directive 669/2009 created a list of FNAO that are classified as “high-risk”, such as basmati rice imported from Pakistan and bananas imported from the Dominican Republic. Like the inspection frequencies in 94/360/EC, this directive stipulates percentage checks, but for identity checks as well as physical checks (POAO require an identity check, so percentage checks only apply to physical checks). However, the list in 669/2009 is more nuanced, indicating specific countries of origin, as well as stipulating the hazard that has led to the product being placed on the list (for example, aflatoxins have been designated as the hazard for basmati rice from Pakistan).

Also, the EU Trade Control and Expert System (TRACES) risk management system, first mentioned by Commission decision 2003/623/CE in 2003 for POAO, has been rolled out across all Member States for FNAO too. This online system was designed to keep track of, and provide veterinary and sanitary certificates for, all animals and POAO, throughout the European Union, allowing for improved traceability. It also contains information about rejected consignments and the reason for rejection. Perhaps most importantly to enforcement practices, EU legislation identifies TRACES as a system that directs physical checks, as well as reinforced checks where required⁵, based upon the trade data that it has accrued. The introduction of the TRACES system, as well as the high-risk checklist in 669/2009, has led to respondents in port health authorities stating that the inspection of food products (POAO and FNAO) at EU BIPs has become more risk-based. As one inspector argued, “It is much more

⁵ Reinforced checks apply to consignments that have had serious or repeated infringements. Usually, this amounts to the physical checks of the next 10 consignments of the infringing product(s) being checked at entry into EU BIPs.

of a risk-based regime, with more high-risk controls, especially since 2010 with high risk of non-animal origin” (Felixstowe_2013).

The terminology of risk for food imports, however, is distinctively different to local food inspection. In local inspection of food businesses, risk is measured in terms of business compliance with food hygiene regulations. By contrast, at import greater emphasis is placed on the inherent risk that the products pose to human health, with high-risk products requiring the full range of documentary, identity and physical checks as described previously.

The focus on checks on food of animal origin has not just been at abattoirs, but also at BIPs. This would explain the use of “high-risk” terminology to describe POAO at import. However, there appears to be some debate over the extent to which this specific regime is risk-based:

They all talk about the need for a risk-base, but there’s a comfort in the current, fairly blunt system. I have to do 20% of fishery products, 50% of meat products or whatever it is, and I’ve got discretion within that, which is where my risk-based approach comes from. Rather than looking at factors like history of compliance for a supplier of meat... or whatever it might be. (FCO_2014)

This view expressed by a respondent from the UK Foreign and Commonwealth Office focuses on the percentage checks that are required at BIPs. Since these checks were laid out in 94/360/EC, which came into force in 1994, there has been relatively little change in the intervening period. This is quite unusual, bearing in mind that in the intervening time, the institutional apparatus of the EU has been realigned following the BSE crisis, and the founding of EFSA has provided an expert-led organisation that would help establish levels of checks that are required. Indeed, from a business perspective, staff from the International Meat Trade Association revealed that they are unaware of the reasoning underpinning the percentage of checks required at BIPs, stating “they are quite arbitrary” (IMTA_2014b).

The discrepancy between POAO and FNAO begs the question, why has there been a greater emphasis on POAO and does this reflect a difference in the risk posed to public health? One respondent confirmed the imbalance between the two categories by stating, “border inspection controls are uniquely focused on animal products” (FVO_2013a). Further

investigation reveals that the focus on POAO is as a result of historical practices, driven by major health scares in the past that have been linked to meat, such as typhoid, trichinella or BSE. As respondents from DG SANTE and the FVO commented:

The problem is that for historical reasons, the probability of having problems in your health with animal-based food was much higher and has been proven by several crises to be the case. So, you obviously look on what you document as a problem. There is a different issue that some of the elements of these problems have been eradicated, and it's very difficult to cut them down from the controls because of traditional feelings that they should be controlled, for example trichinella in meat.
(DG SANTE_2014d)

Meat inspection is historical. The major risk was associated with animal products, and primarily at the stage of slaughter. So, the public authorities, when food chains were much less short and trade less sophisticated, so problems are always in abattoirs... These have always been very heavily regulated, going back decades... Personally I think it has become somewhat outdated, because the risks have shifted.
(FVO_2013a)

A cursory check of major food safety outbreaks in the last century shows why there have been stringent checks on POAO, almost at the expense of FNAO. As explained in Chapter 4, in both case study countries – Germany and the UK – the control of abattoirs within urban centres, and the risk posed from effluence pouring into the street, was more than a passing concern well into the 20th century. Campylobacteriosis, listeriosis and salmonellosis – the three most common diseases related to food poisoning, are often linked to the consumption of contaminated animal POAO. There have also been concerns over whether certain zoonoses can be transmitted from infected animals to humans, through the food chain. Here, BSE is the most well-known example of such transmission, and more recently the possible spread of antimicrobial resistance from farm animals destined for the food chain has led to much international debate and news coverage. Finally, even when the food chain has not been established as a zoonotic pathway to humans, incidents such as foot and mouth, and avian flu, have ensured public interest in animal welfare, and implications for the food chain.

Not only has the historical precedence biased perception of food safety risks towards POAO, the veterinary profession that underpins the checking of food of animal origin is entrenched and this makes it difficult to balance out any checks and balances across food. This view of controls on food of animal origin being predicated on historical, and somewhat outdated practices was confirmed by a respondent from the FVO:

[Through the historical controls on POAO] we created an excellent, permanent sustaining job opportunity, and now you are coming and saying “let’s cut it!”. And those who have to decide on cutting that are exactly those who have these jobs – veterinarians I mean. Would they say we don’t have to do it anymore? (DG SANTE 2014d)

And also, contentiously, it’s a mainstay of the work of the veterinary profession, because all these controls and checks, mandatory presence in abattoirs etc. is the livelihood of large numbers of vets in Europe. (FVO_2013a)

5.3.3 Rapid Alert System for Feed and Food (RASFF)

The EU food import system is incredibly reactive, in that dangerous products that are flagged at import or at a local level will cause alerts to be triggered across EU BIPs to stop their entry into the EU. This reflects the need to maintain the same high level of protection across all 28 Member States, so that food safety risks are quickly identified and communicated across the EU. Central to this reactive approach is the EU’s Rapid Alert System for Food and Feed (RASFF), an information platform created in 1979 and described by the European Commission as follows (EC 2016):

RASFF enables information to be shared efficiently between its members (EU-28 national food safety authorities, Commission, EFSA, ESA, Norway, Liechtenstein, Iceland and Switzerland) and provides a round-the-clock service to ensure that urgent notifications are sent, received and responded to collectively and efficiently. Thanks to RASFF, many food safety risks had been averted before they could have been harmful to European consumers.

This system, which was originally a telephone system but is now online, has produced alerts across a range of food safety incidents, including radioactive contamination of crops because of the Chernobyl disaster (1986); cows infected with CJD (1995); dioxin in chicken from Belgium (1999). In essence, if an imported good is found to pose a risk to public health, it triggers a wave of alerts across all other Member States and their BIPs. One relatively recent example of the RASFF system in action was the 2008 melamine in milk scandal, when it was discovered that milk from China was being adulterated with melamine; a chemical used to artificially increase the level of protein in milk. The adulteration had led to over 300,000 people in China becoming ill. Originally, it was not seen as a threat to the EU as the import of milk or milk products from China was banned. However, the RASFF system detected composite products that contained melamine adulterated milk products, as well as the illegal import of milk products from China. The commission decided to act and within 24 hours, a decision was made to ban the import of composite products from China that were intended for the nutrition of infants or young children (Alemanno 2010).

For information systems like RASFF to operate, a set of controls must be implemented across all designated BIPs, which have efficient oversight across the diversity of the global food trade that passes through EU ports. For the controls to work effectively, and for information to be shared amongst BIPs, enforcement controls need to be tightly harmonised. The single market would be incredibly difficult to operate if a BIP in Italy had a different set of controls to a BIP in Ireland; the freedom of movement of goods within the EU could not be guaranteed without BIPs having a harmonised system of controls with the same risk appetite. Consequently, when Member States choose to place import restrictions outside of an EU mandate, this can have potentially disastrous consequences for the EU. For example, in 2006, following the BSE crisis and the EU's decision to raise the moratorium on the import of British beef, France continued to impose an import ban. The matter was taken to the European Court of Justice, where it was adjudicated that France's continued import ban was unsubstantiated based on the risk posed by consuming British beef. However, had the court ruled in favour of France, there would have been grave consequences for the implementation of a shared import system across the EU, as a senior official at the FVO argued:

Immediately overnight, all those countries [other Member States] would have put a measure in place because their own consumers would have been saying, "the French put in this measure, which is now legally found to be correct, therefore they enjoy a

higher level of protection than we do, go and do something about it”. It would have done catastrophic damage to the European structure and approach to food safety.
(FVO_2013a)

This reaction shows the pressing need for a harmonised approach to food imports, both within the political sphere of negotiations between Member States and in the execution of controls by enforcement officials to maintain a level playing field across the EU. Here, the FVO plays an important role, auditing BIPs, assessing their level of harmonisation and closing down those who do not or cannot enforce official controls in the required manner.

5.3.4 The port health inspector

Port health officers in both the UK and Germany indicated that there was indeed a high level of harmonisation across both ports and these countries. The exception to this rule was when several respondents talked about the presence of a practice known as “BIP shopping”, which may point to a degree of variation in how different BIPs carry out their controls. Essentially BIP shopping is where BIPs will implicitly compete by stating that they can carry out their controls in an expedient manner. This, of course, appeals to importers, because in the commercial world of global trade, time is money. Importers would not wish to have perishable goods in a container at a port waiting to be inspected or verified. As consignments found to infringe EU regulation are either delayed, returned or destroyed at the importer’s expense, formal enforcement action is rarely needed. As one inspector with almost a decade of experience commented:

While inland, local authorities take direct action against businesses, in the case of port health I can’t think of an example. This is because no prosecution is needed, the reason being that consignments remain in detention – all the time a container is sat in port, it costs the importer money. (Felixstowe_2013)

So, it could be argued that the enforcement landscape compared to hygiene inspections of local businesses is considerably less complex, with the outcome of enforcement either being to let goods through, or not. Due to this dichotomy of regulatory action, one respondent from the International Meat Trade Association indicated that port health/veterinary inspectors act more like the police:

But they do see themselves almost as policemen, rather than, I would say, with the attitude of certain local authorities. (IMTA_2014a)

Therefore, the need to strictly enforce a set of regulations that require the utmost harmonisation across BIPs in all 28 Member States brings with it specific challenges, different to those faced by inspectors controlling local food businesses. Central to this is the risk-based system that the EU claims underpins its food import regime.

5.3.5 Co-regulation

The high-risk nature of imports of POAO means that the EU food import regime has resisted co-regulatory drivers, which are becoming an increasingly apparent aspect of local authority enforcement practices (see Chapter 6). A respondent from Felixstowe Port Health Authority denied that co-regulation has made any inroads at all:

Co-regulation hasn't had an impact on import – we haven't seen third party certificates as opposed to EU [veterinary certificates]. The UK might want to see this but it is constrained by the EU. (Felixstowe_2013)

This view was corroborated by a member of the food imports team at the FSA, who said “we have a lack of defence, if we let business regulate” (FSA_2013f). These views are interesting because, under the EU’s farm to fork system, it would suggest that the food chain should be regulated with the same goals being set for each sub-regime. However, this is where the food import regime differs markedly from enforcement practices conducted “inland”. Control systems at import are set very rigidly, with a clear delineation between what is acceptable and what is not, and a clear directive that only EU-accredited systems should be used in the controls.

5.3.6 Ramifications for the inspector

The rigidity of the system, and increasing requirements from the EU for the inspection of certain high-risk products, has been met with some frustration from port inspectors. For

example, a respondent at Heathrow airport stated that the focus on a few products on the 669/2009 list meant there was less flexibility to look at products not on the list:

There is occasional frustration, for example the high-risk list [in 669/2009] ... it's very specific, for example focusing on curry leaves and okra. It could be a wider system. (Heathrow_2013a)

The increased requirements through the implementation of TRACES, on the POAO side, and the high-risk checklist for FNAO, has led to changes to the practices of port health offices tasked with inspecting consignments.

We have to report back [to the EU] a certain number of high-risk checks. This is going to get in the way of us hitting our statutory targets... there is very little flexibility for looking at containers, where local experience may think they might be high-risk. (Heathrow_2013b)

This would suggest a frustration with hitting more statutory targets, and having to disregard what could be subjective insights in relation to enforcing the regime. As another port health authority officer commented, “The danger with all these checks is that you switch off your intuition” (Tilbury_2013) – further direction from the EU will lessen the ability for inspectors to act on their own opinions and experience. However, a member of the FSA imports team did not define this simply as a case of high-risk requirements clashing with inspector intuition and resources, but these new systems better directing the inspector where to look. Having an information-based system like TRACES helps substantially with targeting. Without any such direction, the likelihood for high-risk consignments being missed, due to human error or information asymmetries, is increased, “Focusing on risk means you can forget the random inspection – the back door is closed” (FSA_2013f).

The above quotations indicate that the development of checks for food of animal origin follow a historical precedent, which appears to be incompatible with the current drive to making enforcement practices in-line with developments of risk-based approaches. While there has been a drive across EU Member States to measure compliance of food businesses to food hygiene regulations in local authorities, as well as increasingly rely on internal business systems of audit, the EU import regime continues to focus on hazard.

Table 1. Groups of products and the frequencies of physical checks which must be carried out by each Member State on consignments of products imported from third country establishments referred to in article 1 (94/360/EC)

Groups of products	Frequency of physical check
Category I 1. Fresh meat including offal, and products of the bovine, ovine, caprine, porcine and equine species defined in Council Directive 92/5/EEC 2. Fish products in hermetically sealed containers intended to render them stable at ambient temperatures, fresh and frozen fish and dry and/or salted fishery products 3. Whole eggs 4. Lard and rendered fats 5. Animal casings 6. Hatching eggs	20%
Category II 1. Poultry meat and poultry meat products 2. Rabbit meat, game meat (wild/farmed) and products thereof 3. Milk and milk products for human consumption 4. Egg products 5. Processed animal protein for human consumption 6. Other fishery products than those mentioned under Category I, 2, and bivalve molluscs 7. Honey	50%
Category III 1. Semen 2. Embryos 3. Manure 4. Milk and milk products (not for human consumption) 5. Gelatin 6. Frog legs and snails 7. Bones and bone products 8. Hides and skins 9. Bristles, wool, hair, feathers 10. Horns, horn products, hooves and hoof products 11. Apiculture products 12. Hunting trophies	Minimum of 1% Maximum of 10%

13. Processed petfood 14. Raw material for the manufacture of petfood 15. Raw material, blood, blood products, glands and organs for pharmaceutical use 16. Blood products for technical use 17. Pathogens 18. Hay and straw	
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5.4 Conclusion

Discussion with EU institutions reveals that there is a degree of difficulty in effectively setting acceptable levels of risk across its 28 Member States. However, the EU's own GFL shows tensions with a risk-based approach, as by stating that all unsafe food shall not be placed on the market, it regulates against the hazard (the direct harm caused by the food product) rather than through calculating, and setting a tolerable level of risk.

This tendency towards hazard rather than risk is clearly indicated in the food imports regime, where all POAO is labelled high-risk. This is despite the fact that current risk analysis tools have not been utilised to underpin POAO's determination as high-risk. This suggests that the risk terminology is used for effect, and is as a result of path dependencies from historical practices, and the power of the veterinary interest group, ensuring that POAO is regulated to a high level. Even though systems such as TRACES bring risk management approaches to POAO, they do not override the now decades old system of percentage physical checks.

Chapter 6: Local food enforcement in the UK and Germany

As the previous two chapters have shown, ideas of risk are at the heart of EU policymaking, but for a range of reasons, risk-based policymaking has been difficult to fully implement, not least in the case of food imports. However, ensuring the tight harmonisation of food controls across BIPs is not the full extent of the European Commission's involvement in the promotion of risk-based enforcement practices. Regulation 882/2004 on official controls stipulates that all controls of food businesses should be proportional to risk. The significance here is that food safety is a rare example of where the Commission is involved in regulation that has traditionally been the purview of the Member State, namely the control of food businesses in local authorities. The reasoning for such close oversight stems from the number of high profile food safety incidents that occurred around the turn of the 21st century, specifically the BSE crisis. The commission, in explaining its new approach to food safety regulation, following the publication of the GFL, explicitly referenced the role that such damaging incidents played (EC 2004):

Work to improve food safety is going on all the time, but there has in addition been a major overhaul in the last couple of years. This was a response to headline-hitting food safety scares in the 1990s about such things as “mad cow” disease, dioxin-contaminated feed and adulterated olive oil. The purpose was not just to make sure that EU food safety laws were as up-to-date as possible, but also that consumers have as much information as possible about potential risks and what is being done to minimise them.

The introduction of a “farm to fork” policy was central to this overhaul. The policy is based upon the presence of hazards right along the food chain, from production through to processing, transport, wholesale and retail, and the need to reduce and mitigate any ensuing risks. To achieve this, the Commission needs to have oversight of the safety of food right up until the point of sale, meaning the oversight of businesses within Member States. As discussed previously, historical developments with regard to food imports had put pressures on Member States to ensure the equivalent level of protection (see Chapters 4 and 5), and this had led to a high degree of harmonisation across BIPs before the GFL had been published.

However, 882/2004 ensured the need for risk-based enforcement occurred across both BIPs and the inspection of local food businesses.

We therefore have an EU food safety system that works across national boundaries, whether through the steady harmonising forces of ensuring trade objectives, and most notably a single market, or the much quicker upheaval at the turn of the 21st century caused by food safety incidents. The trend in the 21st century of having directly applicable EU regulations (such as the GFL, 882/2004 and the hygiene package), increases the pressure on Member States to ensure that they are aligned with the EU food safety regime. But how does this play out?

As noted in Chapter 5, it has been difficult for the European Commission to implement risk-based approaches at point of import, and this is indicative of wider discussions across the Member States as to what constitutes acceptable levels of risk and approaches to guaranteeing safe food. So, on an individual Member State level, do the UK and Germany provide a fertile ground for the application of risk-based approaches to the enforcement of food safety? This chapter will explore this question by investigating the extent to which the enforcement of local food businesses is and can be risk-based, in the UK and Germany. The next section will look at the UK's food safety regime.

6.2 Local food enforcement in the UK

As has been discussed earlier in this thesis, the UK food safety regime has embraced risk-based approaches. The FSA has for some time explicitly indicated the desire to implement risk-based approaches to food safety regulation, stating in 2006, “We aim always to be risk-based and proportionate... and aim to reduce risk to the level that would be acceptable to the ordinary consumer” (FSA, 2006). Such an approach to regulation, founded upon risk, has been transmitted to local authorities through guidance provided by the FSA (2012). However, risk-based enforcement has been apparent since the 1980s when local authorities operationalised priority-planning systems to direct inspection frequencies (Demeritt et al. 2015). In recent years, there has been increasing pressure to improve consistency of enforcement practices across local authorities (Fairman and Yapp, 2015). Increasingly constrained resources have further increased the pressure to make sure interventions are targeted upon risk. However, there are constraints to the establishment of a consistent, risk-based system of enforcement in the UK. The following sub-sections highlight certain aspects

of the enforcement regime that contribute to undermining a consistent, risk-based regime envisaged.

6.2.1 The autonomy of local authorities

The UK's food safety framework is highly centralised by the presence of two national competent authorities, the FSA and Defra. In the case of inspection of Food Business Operators (FBOs) by EHOs, it is predominantly the FSA that is the coordinating authority here. As discussed in Chapter 4, the FSA deals with the interpretation and implementation of European regulations and directives, produces the Food Law Guide of Practice for local authorities, conducts audits of local authority performance, and has the power to step in if it feels that a local authority is underperforming. Local authorities set best practice through interaction with the FSA but also through meeting with neighbouring local authorities in regional groups. However, the UK differs from a federalist system as local authorities aren't EU mandated competent authorities, unlike in Germany where the 16 Länder are termed as such. Therefore, the FSA maintains hierarchical oversight.

When asked to what extent local authorities felt they had flexibility in choosing and implementing their own enforcement strategies for food safety, there appeared to be a rather mixed response. Central to this was the role that the FSA's own guidelines had on enforcement practices. The Food Law Code of Practice, a constantly updated document that sets out food safety regulations and good practices for enforcement officers, is utilised to differing extents by different local authorities. Some argue that the Code of Practice is the direct manifestation of Food Law and should be implemented in its entirety:

The Food Law Code of Practice is law; I cannot understand how anybody could think differently – it's in the title! (Huntingdonshire_2014)

Other EHOs argue that it is a set of guidelines, not rules, and as long as local authorities don't contravene the Food Law underpinning this document, then they are at liberty to take a step back from the guidelines as set out by the FSA:

The code of practice is a guidance document, designed to make our lives easier. It is not the exact application of food law; it is only based upon it. So as long as we don't

contravene the food law at all, there's plenty of scope to improve upon the Code of Practice. (Brighton & Hove_2014)

Finally, other EHOs see the Code of Practice as a suitable and necessary foundation that should be added to with original methods of enforcement practice:

The Code of Practice is there for a reason. We're not supposed to tear the rulebook up but that doesn't mean that we can't contribute to it, and help improve it. (Rother and Wealden_2014)

Despite this variance in how the Code of Practice should be interpreted, the EHOs interviewed largely agreed that it fundamentally provides a harmonising basis for their actions. The level of detail that it provides (along with supporting documents), appears to be more a reflection of historic EHO practices, rather than a set of guidelines that were superimposed on existing EHO norms and values.

However, there have been examples of greater local autonomy. One such example is the “Systems Thinking” approach that has been implemented by Great Yarmouth local authority. Until recently, Great Yarmouth local authority was failing to keep up with the quota of inspections that were required as calculated by Annex 5 of the Code of Practice. In 2010, out of the 1,432 food businesses registered, 450 inspections were overdue. The problem was further exacerbated by seasonal increases in people visiting the borough (Great Yarmouth is located on the Norfolk coast, which is popular with holidaymakers), leading to more reactive work. The Systems Thinking approach was predicated by a comprehensive examination of the LA’s enforcement practice. The main outcome was a reduction in the burdens associated with inspecting an FBO, such as reducing the number of letters sent to businesses, reducing computer use, and individual EHOs taking responsibility for the entire process of enforcing an FBO rather than handing the file along to a colleague. However, a more fundamental change to the LA’s practices that came out of this root and branch review related to how EHOs assessed and scored the FBOs.

Great Yarmouth decided to score the “Confidence in Management” section entirely differently from the recommended method set out in the Food Law Code of Practice. As the local authority took the view that the Food Law Code of Practice wasn't law, therefore they

weren't *breaking* the law, they could adapt the scoring system to help improve compliance and deal with the overdue inspections. The argument here was that food safety inspections were far too procedural and didn't address the underlying issue of why an FBO couldn't improve its compliance:

If you're just going around ticking boxes, saying "this FBO has an up-to-date HACCP, so we have confidence in the management, or they don't have a HACCP, so we have no confidence", you don't actually focus anymore on the actual risks – there are plenty of FBOs with terrible HACCP documentation, but great hygiene controls, and vice versa. (Great Yarmouth_2014)

FBOs can be heavily penalised if they don't show the appropriate record keeping and procedural responses to potential food safety risks within their establishments. For example, a business that doesn't have an up-to-date HACCP plan or SFBB (Safer Food, Better Business – see 6.2.2 for a description) plan might be given the second lowest score on the FHRS (1 – "Major Improvement Necessary"), regardless of whether the establishment has scored highly in other categories. The criticism is that the record keeping is just a function of an "audit society" approach that fails to instruct FBOs on why they need to be aware of potential food safety risks and their underlying causes. Great Yarmouth's belief is that by lessening the impact that record-keeping scoring has on inspection frequencies, and instead spending intense periods of time with FBOs with low compliance in food hygiene practices, the potential food risks can be suitably communicated and the FBO can act accordingly. The envisaged outcome is that the same low scoring establishments don't continue to score so low:

We spend a significant amount of time with low performing FBOs, focusing on the risks and educating them, rather than just asking them to fill out forms and leaving. This way, it sticks, rather than constantly coming back to the same issues, time and time again. (Great Yarmouth_2014)

The respondent argued that FBOs are provided with more education rather than asked to take part in a tick-boxing programme that fails to explain its purpose. Great Yarmouth's differing approach to food safety enforcement has led to much debate within the environmental health community. As one respondent made clear:

I think we're seen as renegades by some other local authorities, needlessly messing with the perceived wisdom, and sailing too close to the wind when it comes to Food Law. (Great Yarmouth_2014)

It does serve to show that local authorities can exhibit greater autonomy, although it is necessary to point out that this is sanctioned autonomy, as in the case of Great Yarmouth, whereby the FSA has had to give its blessing to any novel approach. Additionally, the comments from this respondent appear to indicate that Great Yarmouth is the exception to the rule that local authorities have relatively harmonised and entrenched enforcement practices.

It can be argued that novel approaches to local food safety enforcement have been further required due to the current economic climate. Instances of local authorities failing to meet their statutory requirement of inspections are becoming increasingly prevalent. In 2013, Torbay council warned that it was not able to carry out 100 percent interventions in Annex 5 category C establishments (currently defined as requiring an inspection every 18 months), as is mandated (Williams 2013a). Other councils include Brent Council and Worcester Council, which only inspected 45% and 47% of category C FBOs in 2011/2012 respectively (Williams 2013b). Cuts to their funding have meant that local authorities have increasingly been unable to meet statutory requirements for inspection as set out by the FSA.

6.2.2 Implementation of HACCP

As confidence in management is based on food businesses taking responsibility for providing safe food, do enforcement practitioners feel that businesses can deliver on this requirement? The responsibility that FBOs have for providing safe food is clearly enshrined within the EU General Food Law, 178/2002. However, within local authority governance, this responsibility can prove difficult. As stated previously in this chapter, there can be a clear difference between large businesses and small and medium-sized enterprises (SMEs). The potential issues for SMEs, such as lack of resources, lack of expertise and language barriers, can manifest themselves not only in low Annex 5 and FHRS scores, but also bring into question whether certain food businesses have the capacity to take full responsibility for providing safe food. The implementation of HACCP procedures is key to businesses being able to show they can control food safety risks. HACCP has been designed to be utilised along the entire

food chain from farm to fork. Essentially, it allows businesses to identify hazards along their part of the food chain and take mitigating action. Once a hazard has been identified, businesses are required to set tolerable levels for that hazard (Critical Control Points – CCPs), so that public health is not impinged. Businesses are also required to monitor CCPs and establish action plans for when these tolerable levels are exceeded. The issue here is the food industry's ability to implement what is a complex system of self-control. Other than understanding the exact nature of the system, how can businesses get to grips with what a CCP is or maintain suitable levels of control? This is especially problematic for SMEs. In 2012, SMEs accounted for 66.5% of all European jobs, with the accommodation and food sector accounting for 1.7 million SMEs. Research by local authorities within the UK has found that the average reading age for a food business proprietor is equivalent to that of a 12-year-old, whilst for a food business worker, the figure stands at equivalent to that of a 9-year-old. As both EU and national regulators are highly dependent upon the food industry's capacity to implement self-check systems, issues of suitable expertise and understanding will leave an integral part of the farm to fork policy vulnerable and open to abuse.

Opinions put forward by local authorities stressed the difficulties faced by many businesses when it comes to interpreting and implementing HACCP procedures:

HACCP is intrinsically quite a complicated system that is dependent on the user understanding food law and risk. Unfortunately, the vast majority of FBOs understand neither. (Huntingdonshire_2014)

The FSA has tried to alleviate this problem by introducing the Safer Food Better Business (SFBB) packs. SFBB is a checklist that focuses on cross contamination, cleaning, chilling, cooking, and management practices. It is a simplified list of dos and do nots for both the management and catering staff of an FBO, as well as a means of self-audit, designed to encourage staff to better understand and implement their statutory requirements under Food Law. However, EHO respondents felt the effect of SFBB was not sufficient to ensure that all food businesses were aware of their responsibilities and the statutory steps that are required in order to provide safe food. One respondent stated that while SFBB proved helpful beyond HACCP requirements, there was still plenty of room for improvement:

I think SFBB does help to an extent. Many businesses don't have the time or expertise to understand and act upon HACCP requirements. It's an imperfect system though, as it's in many ways a diluted version of HACCP. (Horsham_2014)

Other EHOs found that SFBB didn't deliver what it set out to do:

Does SFBB educate food businesses about how to deal and manage food safety risks? No. It's purely a tick-boxing exercise that negates the FBO's responsibility in providing safe food. (Huntingdonshire_2014)

The argument already put forward by the respondent from Great Yarmouth is that there should be less reliance on self-audit and more time spent explaining the food safety risks faced by FBOs.

This issue also brings into light how businesses should be assessed. Although both central and local governments in the UK maintain that food safety regulation is risk-based, the responsibility of business (which forms a key pillar of UK food safety governance) might indicate that the risk basis of food safety regulation may not be as straightforward as first assumed. The principle that no unsafe food should appear on the market, as mandated by EU regulation 178/2002, is hazard-based. Couple this with the hazard-based implementation of HACCP, which is even more evident within SFBB, and an entire pillar of food safety within the UK is inevitably based around hazard rather than risk. This reveals an important distinction between the process of regulating food safety and the outcomes of food safety regulation. While the European Commission, through EU regulation 178/2002, expects the application of food law to be risk-based, the hazard-based nature of ensuring that no unsafe food is provided on the market, is a clear indicator that the outcome can be anything but based on risk.

6.2.3 Co-regulatory dynamics

Controversy over the risk-based nature of the UK's food safety regime, coupled with issues surrounding the capacity and appetite of food businesses to take on and interpret statutory responsibility, provides a relevant backdrop for discussion within the UK about co-regulation between government and industry. Better regulation pressures have ensured that within

central government and the national competent authorities for food safety, there is a desire to allow businesses to take a greater role in the oversight of their food safety practices. This literal interpretation of businesses' responsibility as enshrined in 178/2002, has led to greater calls for more co-regulation within the food safety regime. Ostensibly, co-regulation reduces the burden on regulatory regimes, especially in the food safety domain where there are complex global food chains. Instead of maintaining costly control systems, regulators can utilise private control and audit systems, which are already in place. Furthermore, regulators sometimes lack the expertise required to set up certain control systems in specific areas – the industry expertise that underpins their own control systems can help alleviate this problem.

There have been several schemes launched by the FSA, or brought under the FSA's remit, that fall under the term co-regulation. The Red Tractor logo is an example of this: a collaboration between the FSA and Assured Food Standards (AFS) that focuses on the delivery of official controls for dairy hygiene in primary production. Farms that are enrolled on the Red Tractor scheme have their inspection frequency reduced, to avoid duplication of effort between the control schemes put in place by the AFS and the statutory requirements laid down by the FSA. The FSA has shown an increased appetite for co-regulation and cites the Red Tractor logo as an example of how co-regulation can work. However, local authority respondents seemed a little more sceptical. First and foremost, we return to the problem of distribution of expertise and compliance across FBOs. Whilst large businesses such as Tesco and Marks & Spencer will have their own control systems in place, replete with food technicians, legal advisors and direct connections to government through lobbyists, set-ups like these cannot be expected throughout food businesses, especially at SME level. The fact that a large proportion of businesses within the EU are SMEs further exacerbates the issue. As one EHO said:

How can SMEs be tasked with further responsibility? Many of them are having enough problems keeping up with the status-quo, never mind talking about co-regulation. (Rother and Wealdon_2014)

How can food businesses accept further responsibility when such a large proportion lack the ability or capacity to interpret food law? There are numerous reasons given as to why FBOs are compliant to different degrees. Difference in compliance can be caused by varying levels of expert knowledge. If the manager and staff within an FBO understand the reasons behind

food hygiene requirements, it could make it more straightforward to interpret the legislation, keep records and implement the necessary changes. Furthermore, within the UK, it is relatively straightforward to be registered as an FBO. There is no requirement for proof of any food hygiene expertise and it only requires the relevant local authority to be informed:

[Given] the ease with which it's possible to start a food business within the UK, is it surprising that so many people struggle at the outset? In the absence of any prerequisite authorisation or licensing systems, you can start a food business obscenely easily in the United Kingdom. We were comparing the hurdles that someone would have to overcome to become a child minder with the hurdles that someone would have to overcome to start a food business. It's like comparing apples and pears. In order to be a food business operator, you fill in a form and send it off to your local council – you are then a food business operator. (Huntingdonshire_2014)

In fact, there have been many examples of FBOs starting up without even informing their primary authority:

It happens countless times where someone sets up an FBO and doesn't even bother informing his/her local authority. (Horsham_2014)

Such low barriers to entry, at least from a food hygiene perspective, help to further explain why vendors can enter the food business with such a potentially diverse range of food hygiene knowledge that can, in turn, affect compliance. The question of resources also arises – one could assume that large multi-national food businesses have the resources to ensure compliant workplaces and employ experts to interpret statutory requirements and even oversee systems of self-audit. An SME, on the other hand, may lack the resources to ensure its workplace is fully compliant, and lack the expert knowledge to raise compliance.

An FBO's level of public presence and its brand might influence the extent to which it strives to be fully compliant, e.g. high-profile businesses will not wish to have a black mark against them and face potential reputational losses. Different cultures of food preparation may lead to FBOs falling foul of statutory requirements – the UK has seen a surge in cuisine from around the world, as well as street food and novel eateries, serving unconventional foods or adopting unconventional cooking methods. This increasing diversity in methods of food preparation

and selection can lead to clashes with established norms of food hygiene regulation. Finally, EHOs have come across language barriers that impact upon an FBO achieving compliance:

It makes it almost impossible when you're trying to educate businesses when they don't speak English. There are plenty of SMEs that have this problem and it certainly is a barrier to informing FBOs about their responsibility and how to prevent food hygiene risks. (Huntingdonshire_2014)

The conclusion to draw here is that there are a range of fundamental reasons as to why different FBOs will be able to comply with hygiene regulations, and how reputational pressures further reflect levels of compliance. What is clear is that EHOs are finding a substantial number of businesses that struggle to understand how they can be fully compliant. This does put into context the scale of the challenge faced by increased levels of co-regulation, and how passing the problem from government inspectors to private auditors doesn't, at face value, address the problem. Rather, it simply passes it down the line.

6.2.4 Consistency across Local Authority Enforcement – the case of Primary Authority

As UK food law is approximately 98% harmonised with EU food law, and with the European Commission taking a greater role in Member State enforcement of official controls (as laid out in 882/2004 and the hygiene package), there has been pressure to ensure harmonisation of control mechanisms across UK local authorities under the banner of improving consistency. Further pressures come from the perspective of consumers and the food industry. The advent of publicly available food hygiene scores through the FHRS (see Chapter 7 for a detailed discussion) has served to highlight the fact that different EHOs within different local authorities could score establishments quite differently. Regarding consumers, how can someone visiting a restaurant in Newcastle ensure that controls have been enacted in the same way as in Leeds? If both the Newcastle restaurant and the Leeds restaurant both scored 3 out of 5 on the FHRS, have the scores been reached via the same processes? And with the food industry, how can one business be sure that it has been evaluated in the same way as another business in a neighbouring local authority? The problem further persists when businesses have branches across different local authorities, making it more difficult to deliver a centralised action plan with different authorities looking out for different things.

It can be argued that subjectivity is the basis for making imbalanced decisions across local authorities, and even within local authorities themselves. EHOs accept that a significant portion of an inspection is subjective, as opposed to objective:

At the end of the day you have to make the call on many aspects of a food safety inspection. Sometimes this won't be based on easily objectifiable data – in that instance, you use your experience and instincts. (Huntingdonshire_2014)

An expert judgement must be made to determine the scoring categories for each aspect of an inspection. While best practice is discussed with the FSA and regional coordination groups, variance can occur, even between EHOs within a local authority:

As our food safety manager, I have to constantly work on making sure that we, as a local authority, are working as consistently as possible – that's a constant endeavour. (Rother and Wealden_2014)

The introduction of the Primary Authority Scheme (PAS), aims to alleviate issues of consistency in relation to food businesses that have branches across local authorities. The businesses can now nominate a local authority (designated the primary authority) to help develop and oversee its control mechanisms and auditing procedures. The idea here, is that in coming up with a centralised action plan approved by the primary authority, EHO inspectors across all the branches must follow what is laid out in the Primary Authority agreement. This tends to mean asking local EHO inspectors to enact paired down enforcement activities, as the primary authority agreement disregards the need to ascertain confidence in management on a local level, when it has been assessed centrally.

From the perspective of the FSA's Better Regulation Taskforce, this approach is seen as beneficial for three reasons. Primarily, it backs their push for greater co-regulation and reducing the burdens on business, through working with them to come up with a suitable course of action. Secondly, it reduces the burden on local authorities as it stops duplication of action across business branches that employ the same set of controls and auditing procedures. Thirdly, it also emphasises the risk-based nature of the enforcement approach, as enforcement resource can be directed to businesses that are not part of such a centralised scheme.

According to respondents from local authorities interviewed for this thesis, the Primary Authority Scheme has generated mixed reviews. A significant reservation was the potential for regulatory capture. The argument put forward here is that businesses are hardly going to nominate local authorities who have been giving low Annex 5 and FHRS scores and taking high levels of enforcement action, instead opting for local authorities with which they have a close relationship and have received high scores and low enforcement action from. As one EHO said:

I suppose that can happen, yes, there are examples of where businesses have chosen local authorities they've had a long working relationship with. (Rother and Wealden_2014)

However, this view has been refuted by other EHOs, who have argued that food businesses aren't put off by local authorities who push a harder line. As many food businesses welcome the guidance and education provided by local authorities, they would much prefer to partner with authorities who actively try to drive up compliance, rather than accept what is already in place.

It can go the other way. Maybe a business doesn't want a local authority that is a soft touch. Many businesses value the input of EHOs and certainly wouldn't want to be saddled with a lame duck. (Huntingdonshire_2014)

It might be the case that there is a distinction here between active education and active intervention. While a food business may indeed appreciate further time with EHOs, it is hard to imagine that businesses are equally as content if they and their local branches constantly face enforcement action.

One aspect that all the EHOs interviewed largely agreed on, was that the Primary Authority Scheme took away a measure of independence from EHOs inspecting a Primary Authority scheme's branch. This issue drew some strong criticism from EHOs, as shown here from one respondent:

It really annoys me. I know what's happening in my local area, how each individual FBO complies. Why should a local authority from the other end of the country tell me

what I can and can't suddenly do, just because I happen to be inspecting a Primary Authority FBO chain? (Great Yarmouth_2014)

How could a Primary Authority know with any certainty how a branch of a business in another part of the country is performing? Yes, branches may have the same control systems in place, but these could be interpreted differently branch to branch, or implemented with differing levels of effectiveness. One respondent spoke about this:

At the end of the day, every chain is as strong as its weakest link. Could you say with absolute certainty that every branch of Tesco is managed in the same way? Of course not. (Huntingdonshire_2014)

EHOs build up relationships with their local businesses to the extent that they are intimately acquainted with their management practices and cultures, a level of detail that is difficult to extract from company-wide auditing or from data obtained by the Primary Authority. If an EHO feels that he/she should investigate or act upon a certain aspect of an FBO's procedures, that EHO does not want to be constrained by Primary Authority considerations:

If I know something's wrong, I'm going to incorporate it into my inspection, even if [the] Primary Authority tells me otherwise. (Rother and Wealden_2014)

Finally, the Primary Authority Scheme removes a substantial amount of subjectivity from inspections, as part of what would be covered within an inspection is now overseen by the auditing capacity of the primary authority. This can lead to greater harmonisation of controls, which benefits businesses having to deal with multiple local authorities. But is the removal of subjectivity seen as entirely beneficial? Some EHO respondents argued that inspections shouldn't be subjective and based upon a clearly objective list of interventions:

How can we achieve consistency across the UK if everyone is enforcing rules through rules of thumb? Objectivity is vital. (Brighton & Hove_2014)

However, other EHOs argue that subjectivity forms an important part of an EHO's inspection and allows for nuanced approaches to both interventions and in building a relationship with

business owners that goes beyond the basic tick-boxing exercise associated with scoring an inspection. As one EHO stressed:

We are required to bring our experience and expertise to FBOs who need it, otherwise everything would be some crazy tick-boxing exercise – it's never as simple or straightforward as that. (Great Yarmouth_2014)

So, whilst reducing subjectivity might improve consistency across local authorities, it may also lower the quality of outcome that emerges from an inspection.

6.2.5 Regulatory connections between national competency and local enforcement in the UK

The relationship between the FSA and local authorities is of great importance in delivering harmonised food safety regulation within the UK. As the FSA produces the Food Law Code of Practice, as well as acting as a coordinating body across all local authorities, it has a profound effect on the role played by local authority inspectors. It is therefore interesting to investigate whether, through the eyes of its local authority partners, the FSA can be as risk-based in its governance as it aspires to be:

The FSA does go back and forth when you try to figure out exactly whether it is entirely risk-based. (Huntingdonshire_2014)

EHO interviews paint a fascinating picture of how institutional barriers mean that the FSA cannot be as risk-based as it wishes to be; indeed, it is local authorities who appear to be pushing for more risk-based approaches when it comes to FSA advice and guidance.

One of the main differences between national food safety regulation and local food safety regulation in the UK is around varying levels of accountability, and expectations of accountability. Following the BSE crisis and the dissolution of MAFF, one of the key responsibilities of the newly formed FSA was to restore public trust in the UK's food safety regime. This responsibility was clearly evidenced by the stock the FSA put into consumer reports, its own consumer confidence indicators, and the increasing importance of risk communication and stakeholder participation. Having asked local authorities whether they

needed to restore confidence in local food safety regimes, the answer was a clear “no”. As one EHO summarised:

No – following on from the BSE crisis, we didn't have members of our community come up to us and make demands or say we'd lost their trust. For us, things continued on as normal, which I guess was a far cry from what was happening at MAFF at the time. (Huntingdonshire_2014)

The centralised nature of the UK's food safety regime means that national competent authorities take increased responsibility for national food safety incidents. This heightened level of accountability that is exhibited within the FSA, but not (at least to the same degree) in local authorities can have a profound impact on the regulatory regime that the FSA is required to underpin. It can be argued that the FSA is exposed to public accountability much more often than its local authority partners. As an FSA employee dealing with local liaison noted:

We've become a 24/7 agency. The news now runs 24 hours a day, so do we. We have to be prepared to deal with incidents the very second that they occur. (FSA_2013g)

Issues surrounding media amplification of risk and pressure to implement tombstoning regulation, as described in Chapter 2, can lead to the FSA being far removed from a risk-based footing. One such example, according to local authority staff interviewed, of the FSA undermining the risk-based approach it purports to, is of the initial *E. coli* guidance that was introduced in the wake of the death of 5-year-old Mason Jones in 2005 due to the O157 strain of the virus. This food safety incident was the second biggest UK outbreak of *E. coli*, with 44 schools affected and 150 people (mainly children) falling ill. All the schools affected were supplied by butcher William Tudor, and during the 2010 inquest into Mason's death, the coroner concluded,

I have agonised over a verdict of unlawful killing but despite substantial, some might say horrific, breaches of food hygiene regulations the evidence is not strong enough... There is little doubt Mason was owed a duty of care and a catalogue of failures to observe basic food hygiene breached that duty. Mason's death was a result of an E. coli infection due to the consumption of cooked meat which had become contaminated

during the course of preparation due to a lack of, or disregard of, good food hygiene practices. (BBC 2015)

Tudor was prosecuted in 2007 for breaking food safety laws and sentenced to one year in jail. The FSA, Meat Hygiene Service and local authority (Bridgend County Local Authority) were criticised in the publication of the Pennington Report following the outbreak. The report found that the local authority was deficient in assessing Tudor's management of food safety, and had insufficiently analysed his HACCP plan, as well as failing to assess whether the procedures and plans under his HACCP plan were being put into place. The FSA was criticised for conducting an audit only 18 months prior to the outbreak (as well as taking a year to send the audit report to Bridgend), and finding nothing wrong with the local authority's inspection and enforcement regime (Pennington 2009). The FSA, in its response to the Pennington Report, as well as strengthening the audit skills of inspectors and stressing the importance of HACCP and SFBB, stated:

[The] revision of the Food Law Code of Practice, which sets out a framework for enforcement interventions/approaches... re-emphasises the need for a risk-based, proportionate approach to inspection. (FSA 2009)

The need for "re-emphasis" on a risk-based, proportionate approach is particularly interesting, considering the FSA's *E. coli* guidance that was subsequently released. One of the clear breaches of good food hygiene practices enacted at Tudor's butcher was the use of the same machines for cooked and uncooked meats without proper cleaning in between. This was picked up in the Pennington report, as well as by the press (BBC 2010). The outcome here was that in the FSA's ensuing *E. coli* guidance, complex food preparation machinery, such as vacuum packaging machines, could not be used for both raw meat and ready-to-eat food. This was deeply problematic for two reasons: the first was that many relevant establishments, especially SMEs, could not afford to have one version of an expensive machine for raw meat and another for ready-to-eat food – FBOs simply cleaned their units in between. Secondly, the FSA failed to provide any substantive science-base to justify this decision. The following quotations from EHOs indicate their concern at the guidance produced:

Where was the scientific basis to the FSA's decisions? They certainly didn't provide us with the details. To be honest, the guidance was quite mad and got quite a few EHOs angry. (Huntingdonshire_2014)

It was as if the FSA had never experienced what enforcement – and the goal of enforcement – was all about. The guidance lost track of reality and there was not a chance most of it could be realistically implemented. (Great Yarmouth_2014)

Therefore, the FSA produced a reactionary piece of guidance without necessarily considering the full costs involved or providing suitable public health reasons as to why such guidance was necessary. This left many to assume it was introduced purely due to reputational reasons, with the FSA trying to ensure the public's confidence in food safety was not too adversely affected. This, one could argue, is not the "risk-based, proportionate approach" that the FSA was advocating so soon after the incident.

As well as the institutional risks to the FSA created by media amplification, the desire to be entirely risk-based and based upon the best available science can also drive the agency to inaction. Such an example is the recent advice, or lack thereof, to local authorities on the intervention required for FBOs that serve mince-meat cooked to a medium-rare or rare standard. As an EHO explains:

We're increasingly getting more of these up-market burger joints popping up that want to serve burgers rare/medium-rare, despite the risk of E. coli [due to the use of minced meat not being cooked all the way through]. We're waiting on guidance from the FSA but they're nowhere to be seen. (Rother and Wealden_2014)

Despite this practice being widespread, at the time of interview, local authorities were still waiting on FSA guidance. However, the FSA refused to provide such guidance until it had collected substantial data on the problem, leaving local authorities somewhat in the lurch as they did not know how to progress. This has led to EHOs accusing the FSA of being contradictory in its approach to its risk-based doctrine:

With the FSA, it comes out with the E. coli guidance, which is anything but based on risk. And then we're left waiting on the guidance on rare cooked burgers, whilst the

FSA conducts its assessment, despite there being clear and present danger now. The FSA seems to flit from being overtly hazard-based at one moment, to overtly risk-based on the other. (Horsham_2014)

In defence of the FSA, it does have a very demanding remit. Ensuring the safety of food sold and consumed within the UK, and restoring and maintaining public confidence in the UK's food safety regime are often seen as two mutually exclusive commitments. This is especially the case when the agency wants to implement a scientifically evidenced risk-based strategy in the face of a domain that is constantly exposed to media amplification and consumer fears. EHOs interviewed did state that the FSA is getting better at liaising with local authorities, seconding EHOs into the agency and ridding itself of the ivory tower label that some ascribed to it during the first few years of its existence. One EHO felt that communication and cohesive action was improving:

There's no doubt that the communication lines are getting better. The FSA is starting to listen more to the needs of local authorities. (Huntingdonshire_2014)

There is still some concern exhibited that the FSA is a civil service dominated institution that needs staff with the necessary environmental health expertise to ensure that any guidance issued is given with local enforcement context in mind. As one local authority respondent stated, although the FSA has the power to step in and take over from an underperforming local authority, it most likely wouldn't:

I don't think the FSA would be able to step in – it lacks the expertise. While there are EHOs seconded to the organisation, the majority are still civil servants, who wouldn't have the first idea about local authority inspection. (Huntingdonshire_2014)

Finally, the FSA's audit system, so heavily criticised in the Pennington report, still appears to receive mixed reviews. Whilst some local authorities speak of the benefits of FSA guidance following an audit, there appear to be missed opportunities as lessons learnt, or best practice stemming from these audits, are not effectively shared with other authorities:

FSA audits are useful, they help identify key issues within a local authority's capacity, and the FSA will then act appropriately... I suppose though, we don't get to see the

audits of neighbouring authorities. I guess it would be useful with regard to setting best practice. (Huntingdonshire_2014)

6.2.6 Problems of sampling

One key element of a risk-based regulatory regime is the data that informs risk assessments within the information gathering stage. All local authority interventions and emergency callouts are logged and, where appropriate, fed into the Rapid Alert System for Feed and Food (RASFF). Therefore, depending on the severity, local, national and European authorities can be made aware of any food safety emergency, and can ensure that relevant authorities are made immediately aware. However, on a day to day basis, an important means to providing risk assessors and policymakers with information, is sketchy at best. The sampling regime for many local authorities interviewed is far from robust. In part, due to the resource constraints placed upon EHOs, it would appear that enforcement actions are heavily prioritised over sampling procedures. There was a large degree of apathy when discussion turned to requests made for sampling from analysts:

We sometimes get some unusual requests – you end up going to a Tesco Extra [a large supermarket] to find the food the sample needs to be taken from.
(Horsham_2013)

If samples are taken from large FBOs, which likely have more intricate internal audit and food quality systems than small businesses that may have lower levels of expertise, are such samples suitably indicative of microbiological or chemical risks throughout the local authority? The regime here is not presented as suitably connected and begs the question that if local authorities fail to see the importance in the sampling requirements, a key facet of the regulatory regime is found wanting.

6.2.7 Constrained resources

Finally, one further area of note with regard to the risk-based regimes of local authorities, is the extent to which enforcement activities may be scaled back in the future. A combination of constrained resources, better regulation initiatives and co-regulation has indicated that, while central government intervention in food safety is being rolled back, it occurs, and will

continue to occur, at local government level too. Although EHOs accept that this trend will continue, of the EHOs interviewed, the argument is that it can only go so far. For comparison, routine inspection within the domain of health and safety has been rolled back, with more responsibility placed on businesses to inspect and maintain their health and safety controls. Such a scenario cannot occur as seamlessly within food safety as the reliance on expert knowledge is much greater and the reasons for maintaining many food safety controls are not clearly apparent to many FBOs. As one EHO made clear:

In health and safety, it's much clearer and straightforward. It's fairly obvious that when you're on a building site, you wear a hard hat. Whereas with food safety, it's much harder – for many of the risks faced by FBOs and the public, you'd need a microbiology degree to truly understand and appreciate what's going on. (Great Yarmouth_2014)

This highlights the fact that food safety inspections are not only for checking that statutory controls are in place, but in many cases, providing the education so that FBOs are aware of these controls and know how to abide by them. Indeed, several EHOs stressed how many FBOs, especially those with limited resources and expert knowledge, welcomed EHO interventions, as they helped plug significant knowledge gaps:

In the main, we're welcomed with open arms. FBOs take the opportunity to learn from our expertise and the majority of them wish to be respectable companies that are compliant with our food law, so many of them welcome interaction with us. (Huntingdonshire_2014)

In conclusion, it is very hard to see the development of interventions within food safety progressing in the same manner as within the health and safety domain.

6.3 Local food enforcement in Germany

Continuing the theme from the UK section, Germany has also seen attempts at trying to increase consistent use of risk-based enforcement practices across its 16 Länder. In response to the need for risk-based controls in 882/2004, the federal German food safety regime has implemented these requirements in administrative proceedings. Central here is the

requirement for the inspection frequencies of food businesses to be risk-based, as laid out in the General administrative instructions on the principles governing the performance of official controls on the observance of food, feed, tobacco and animal legislation (AVV-Rüb). However, because the Länder are competent for enforcement of food safety, despite the presence of general administrative guidance, there can be a great deal of variance of enforcement practices across Germany. This section will present some of the key outputs of the research that indicate how consistency across Germany is difficult to attain, and how regional risk appetites make it difficult to realise a single German enforcement risk regime fully harmonised under the broader EU food safety regime.

6.3.1 The evolution of inspection practices within Germany

In Germany, the evolution of food inspectors presents an insight into how risks identified at food businesses have been managed by local authorities. As has been discussed, Germany has seen a great deal of variation in who has been tasked to carry out inspections of food businesses, far more so than in the UK. While the veterinary and food chemist professions have come to play a leading role in local food safety enforcement, the role of the police has ebbed away, being replaced by specialist food inspectors who invariably have a background in the food industry. According to respondents, this development has had a significant impact on how inspections are carried out.

The last Land to dispense with police officers as front-line inspectors was Baden-Württemberg in 2006. As this was relatively recent, it offered an excellent opportunity to investigate whether enforcement practices had changed since Baden-Württemberg had fallen into line with other Länder by employing specialist food inspectors. While these police officers were given further training in food law and practices, and were part of a specialist section (*Wirtschaftskontrolldienst* – WKD), respondents in Baden-Württemberg could articulate differences in the approach to enforcement between the WKD and the specialist food inspectors that are now being employed. In particular, there appears to have been a shift from a more command and control approach to enforcement, to a softer compliance-based approach:

[Police inspectors] would say, “if you don’t do this, you will get a fine or you will be arrested”. Now there is a different approach, “yes, I know [where you’re coming from], I’ve had experience, maybe you should do it differently”. (BW_2013)

Another respondent tempered the statement somewhat by saying there was variation across police inspectors:

Yes, there [were] some [police inspectors] who acted like you see in the Hollywood films, “put your hands up, you’re under arrest!”, who saw non-compliant managers as criminals... But the level of knowledge is different. Police inspectors go into a business and say, “you clean the walls up to this level” but wouldn’t explain why, now it is different... When it comes to bad tricks, for example adding weight or additives to food, new inspectors who have a background in the trade will spot this, more than the police before. (Stuttgart_2014)

The respondent working for the Baden-Württemberg government stated that now, unless an FBO was doing something obviously wrong, the food inspector would likely only suggest changes, rather than explicitly saying what is right and wrong. Enforcement therefore appears to be more principle-based than prescriptive, which would reflect the situation in the UK. However, in contrast to the approach taken by UK EHOs, that is not to say that inspectors are an on-tap source of information for food businesses trying to understand the law, especially with SMEs as the following example makes clear:

SMEs have a problem that owners have no idea about food laws or hygiene... they ask us “can you explain to me how to do it?”, that’s none of our business, there are private enterprises that train them. We can only say to them to go to the IHK [Chamber of Industry and Commerce] and we try to give the business some basic information. (Stuttgart_2014)

The reluctance of the food inspector to engage in providing education for FBOs can perhaps be explained by two points. First, there may be a hangover from the command and control approach conducted by police forces. There, the priority was to identify and enforce clear violations of the relevant law. Providing education would have been somewhat challenging as police inspectors would not necessarily have had a background in the food trade. Modern

food hygiene inspection, despite having increased expertise, may have continued the tradition of focusing on violations. Second, the corporatist nature of German policy-making and administration means that the predominant source of information for food businesses lies with the trade bodies that represent them, especially the IHK. This points to a clear delineation between those inspecting and those inspected, despite the food trade background many German food hygiene inspectors have today. It further reinforces the separation of functions that underpin the German corporatist tradition, as opposed to in the UK where different regulatory functions are found within the generalist nature of EHOs.

One would assume that the combination of the EU's General Food Law stance that all food placed on the market must be safe, coupled with the German approach to precaution (*vorsorge*), would ensure that food inspectors would seek to regulate any activity deemed unsafe. However, there appears to be much greater freedom regarding the risks that food inspectors deem to be acceptable or unacceptable:

According to German law, everybody who gets sick from eating my food... I have hurt these people, just like if I have run them over with my car. But if the operator can prove that he has reduced the level of risk the best he can, as long as people order the food, they [the consumers] decide they want it. But still, if the people who get ill and spend several weeks in hospital, the food operator has to pay the hospital costs and cover lost income during that time. And he might get fined by the [local] attorney.
(Stuttgart_2014)

While the above comment shows strict liability for the food operator under German civil law, it also shows that food inspectors may permit certain actions so long as the operator can show he/she has done whatever necessary to reduce the level of risk. This is consistent with the "As Low as Reasonably Practicable" (ALARP) mantra that is prevalent in policy domains such as health and safety, but may be inconsistent with the notion of *vorsorge*. Continuing with a process or product that could lead to having to cover a customer's loss of earnings through illness and potential fine, may act as a deterrent to food operators. But this approach explicitly accepts a level of risk that a precautionary stance may not tolerate. The practice of ALARP on a local enforcement level appears to be in contrast to standard setting at a national level, where, as Chapter 6 makes clear, federal regulators find it difficult to adopt an approach that does not ascribe to the principles behind *vorsorge*.

6.3.2 European regulations at the coal face

The allusion to “rigorous” audit mechanisms is indicative of the case that all 16 Länder have different auditing procedures in place, that can inevitably capture different types of data through differing methodologies, rendering the possibility for comparison and analysis across the federation problematic. The question here, is how can Germany harmonise European regulations and directives across its constituent states, when the information gathering aspect of its regulatory regime is so fragmented? This problem is indicative of why it takes Germany so long to implement changes from the European Commission, compared to non-federalised states. Not only does federalisation mean that messages have to be transmitted and successfully interpreted across 16 different competencies for food safety enforcement, but standardising the results of oversight across the federal Länder requires a great deal of time. As one respondent in BMEL commented,

[With regard to] implementing EU regulations, there always seems to be one third of the country lagging behind. When a decision is being made at the Commission, as a country, we cannot give a definitive answer, we have to go back and check with all the Länder. This is a very slow process.

This point of view has also been reflected in the European Commission itself:

There is a big difference between federalised Member States, like Germany, and more centralised ones. You have to be much more patient. (DG SANTE_2013a)

The EU’s own auditor for food safety matters, the FVO (see Chapter 4), faces similar problems to the German federal court of auditors. It would be unrealistic to suggest the FVO must inspect every Land. However, because each Land is competent for the enforcement of food safety controls, as opposed to the UK where a centralised agency still holds such competency, and therefore liability, the capability for a Land to differ from those Länder that have been audited can be greater, according to a Länder authority respondent (Saxony_2013b):

Yes, I think there will be inevitably more variance across the federal states.

Germany's position as a federal state acting within the federal system of the European Union not only has implications for how the German federal level implements European law, but also for enforcement of regulations and directives at a local level. Several respondents across different Länder talked about the difficulties here, for example:

There is a big difference [in enforcement practices between now and before the EU hygiene package of regulations], as the law is so much harder to read. 852, 853, 854 have complicated things, as well as the gaps that need to be filled by national regulation. (Stuttgart_2014)

The introduction of direct European regulations through the hygiene package (which has been discussed in Chapter 4), has added a further level of complexity to the distribution of competencies between federal, Länder and local levels. The highly juridified nature of German food safety regulation means that any enforcement actions taken on a local level must sit with the letter of the law as implemented on both a national and state level. Therefore, implementing EU regulations can lead to periodic difficulties for enforcement actions. Referring to the hygiene packages, the same respondent described such a situation:

There was this legal gap between 2006 and 2008, as there was no German regulation that showed how to find non-compliant food business under EU law. We can only go [to a business] and say "you have to improve" and that was it, we couldn't [impose] fines on many things. (Stuttgart_2014)

This was clearly an unwanted state of affairs and highlights the difficulty that Germany as a whole has in implementing regulations across its 16 states. A respondent working for the Bavarian Land emphasised the difficulty of implementation, but stated that it was not just down to the interpretation of law but also the active role that the Länder play:

It might be that Germany is slow in implementing the law, because all the Länder want to be involved in the discussion. (Bavaria_2013a)

Länder are not only involved in federal policymaking through the Bundesrat and less formally through coordination committees, they can also send delegations to the European Commission. This means that Germany does not just experience political fragmentation on a

national level, but also on a supranational level as well – further highlighting the important role that Länder play in standard setting, and underlying the caution with which supranational law is converted into national and local law.

This is not to say that fragmentation within Germany should be interpreted as Länder stubbornly working entirely for self-interest, and stifling the passage of European and German law. In the case of food safety, there have been clear attempts to increase dialogue across the Länder. As previously discussed within this chapter, one of the core competencies of the BVL is to facilitate discussion and best practice across the Länder. Also, following on from German reforms at the start of the century, specialist food safety committees known as LAV have been set up. These involve relevant civil servants from each Länder, as well as representatives from the federal government, and meet on a regular basis and during times of emergency. This more robust form of organisation has increased levels of consistency, as was made clear by a European Commission respondent (JR):

Germany is now much better at setting best practice across its states. The introduction of Länder committees [the LAV] has really helped in this. (DG SANTE_2013a)

Such consistency has seen the Länder uniformly adopt the same risk assessment system for scoring food businesses, as well as working towards a means of comparing Länder systems and implementing change across the Länder following recommendations received from an FVO audit.

However, there are substantive differences between the Länder, and according to a respondent from BMEL, these differences explain the reticence of Länder to engage in much transparency with regard to their food safety regimes, despite their claims of greater harmonisation through best practice committees:

The official version is that they're trying to harmonise, that they're trying to compare each other, that they're trying to define criteria on how they do official controls to unify it much more, to harmonise it much more... This is why they have started some activity in auditing, and [compare the auditing systems]. On the other hand, there is also some tendency that the Länder are too afraid of transparency. It is a fact that

some people tend to look at others and compare themselves, for example Bavaria will say they have the best system, and they've got quite a good system, and they're also financially better equipped than other Länder. [But] as the quality of the control systems is not the same in all the Länder, that's why they're a bit hesitant and a bit restrictive with too much transparency. They've noticed the need for some transparency and harmonisation. On the other hand, every Land is independent and has different leaders and a different financial situation. (BMEL_2014a)

Even though there have been strides made to ensure that food safety authorities across the Länder work closer together, further efforts might be needed to achieve a higher level of harmonisation. On the other hand, there are fundamental differences that the Länder may not wish to present through greater transparency. One opinion offered by the BVL was that the more local the level in Germany, the more freedoms should be realised:

When you really want to have a good control, this control must not be standardised at a 100% level, there must be something free to do unusual things. You can standardise the upper level, no problem. But the further down you go, you need more freedom, more freedom, more freedom. (BVL_2013)

Such local freedoms are protected to a certain degree in how the federal level has delivered its guidance for enforcement approaches through the AVV Rüb, as it is deliberately vague. The AVV Rüb's only real detail, allowing it to be enacted in administrative law, is the need to take 5 samples per 1000 members of the population. Otherwise, the AVV Rüb states that the Länder should work together and ensure that enforcement practices are based upon risk. However, the lack of a clear steer from the federal level does not appear to be at its behest:

It would be probably impossible that [what] we put down in the AVV Rüb [we put] in a real law. Because all these matters we deal with in the AVV Rüb are controversial with the Länder. We have many ideas that we would like to practice, but we would have to pay for that... That's the permanent conflict we always have in this field. (BMEL_2014a)

Discussions over who should have competency between the federal government and the Länder has clearly created a constant point of tension. These tensions come to the fore when a national incident occurs, as was the case in the wake of the 2011 *E. coli* crisis.

6.3.3 Constraints of institutional architectures on risk-based enforcement

The 2011 STEC *E. coli* outbreak in Germany, which had the vast majority of the 3,935 reported cases and 50 deaths in Europe (EFSA 2012), was a clear indicator of the lack of consistent action across Germany, despite the organisational reforms that were supposed to present a clear approach to food safety risks. From the federal level response, down to the disparate reaction from the Länder, the *E. coli* outbreak served to highlight that reforms made in the wake of the BSE crisis did not sufficiently tackle the structural deficits of Germany's food safety regime. To begin with, there was no apparent central leadership when the first cases of *E. coli* were discovered. BMEL might have taken this role, but it must be noted that with the autonomy afforded to the Länder within the federal system, federal oversight and control has weakened as a result:

We have always asked for more responsibility. But this is difficult as the Länder would need to agree to a change in federal law to accommodate this and why would they want to do that? (BMEL_2014b)

And BMEL was not the only federal level institution that was caught out. Although the BVL had been assigned coordinating responsibility during a large-scale food safety incident, there was confusion as to whether a crisis response team should be formed within BVL or other federal agencies. As for the BfR, which had (and still has) a clearly defined risk communication remit (though strictly risk assessment as opposed to management decisions), its role during the *E. coli* crisis was equally confounding:

We had members of the public calling us up asking what should we do? Who should we talk to? And we realised that we hadn't formalised any response. We ourselves didn't know what responses we should give to the public or even what our role during such a crisis is. (BFR_2013)

A lack of co-ordination across the Länder was clearly evident. Hamburg, one of the first states to experience the outbreak, immediately communicated the first cases of the outbreak before consulting other Länder or the federal authorities. In trying to indicate the cause of the outbreak as soon as possible, erroneous sources were indicated, culminating in the accusation that Spanish cucumbers were responsible. The situation developed so quickly that federal authorities didn't have time to react and individual Länder were taking responsibility for communicating the risk for what was a major national incident. Even in the aftermath, Länder and federal authorities still did not appear to be acting cohesively, as a Hamburg civil servant argued against the findings by the federal government:

We still haven't been shown the evidence that Egyptian beansprouts were responsible for the E. coli crisis. I believe we [the Hamburg government, in pointing the finger at Spanish cucumbers] did nothing wrong and the truth is still out there.

(Hamburg_2013b)

Since the *E. coli* crisis, it has been a priority of subsequent Merkel-led governments to further strengthen cooperation between the German Länder and the federal government, stressing the need for a co-ordinated approach to food safety incidents, establishing a crisis response team within the BVL and running a national exercise to test co-ordination and response mechanisms to crises, known as LÜKEX⁶. The LÜKEX exercise focused on food-borne biological outbreaks, with a simulated outbreak of pneumonia in Berlin, and gastroenteritis nation-wide. Respondents from both the federal government and Länder authorities claimed the exercise a success, clearly showing that a coordinated response to a food safety crisis has become more apparent. The creation of the BVL crisis taskforce is a relatively rare example of the federal level taking greater responsibility within an aspect of food safety regulation. Unlike the regular day-to-day role that the BVL plays in facilitating coordination amongst the Länder (though not influencing the decisions the Länder make), the BVL takes a much more active role here. The logic for such a centralised taskforce reflects the fragmented status of food safety regulation in Germany, with concerns that, previously in a large crisis, Länder

⁶ LÜKEX (*Länderübergreifende Krisenmanagementübung Exercise*) is a series of approximately biannual exercises that test crisis management across Germany and its Länder, with a first test in 2004 looking at power failure, flooding and terrorist threats at sea. Subsequent tests have covered a wide range of possible threats, from cyber-terrorism to the dangers posed by Germany hosting the 2006 football World Cup.

authorities were pushing out their own crisis communication, which may have contradicted each other or the federal government. The taskforce also shows the desire from the federal government to take a more prominent role in crises, not simply in relation to the Länder, but also in coordinating federal ministries and their agencies.

6.3.4 Variance across the German Länder

Due to the high level of autonomy for the Länder, Germany faces a great challenge in dealing with national food safety risks. Because different Länder have competency for the enforcement of EU-derived food safety controls, different methods of control have developed across the country. Expectations about what constitutes a protective level of food safety have therefore differed. One avenue of inquiry was to ask if there are fundamental differences between these expectations in the Länder that were formerly part of West Germany (the Federal Republic of Germany), and those of East Germany (The Democratic Republic of Germany). On the one hand, there was consensus that a whole range of policy domains, including food safety, needed to be considered following the reunification of Germany, indicating historical differences:

It was a process of some years, that in every field of policy-making, on every field of administration that had been in the past of two separate republics, they had taken different developments. But after three or five or six years after reunification, I think it has got into relatively the same level. (Hamburg_2013b)

However, the response from respondents who operate in Länder that were part of West Germany indicated that there is now no difference as a result of the former separation, as was expressed in Hamburg:

No, I don't see any major social or cultural difference between the former East and West that could account for a difference in expectation. (Hamburg_2013b)

And also expressed in Baden-Württemberg:

I can't think of any cultural differences between the West and East. The makeup of food businesses might lead to different enforcement actions. (BW_2013)

However, when speaking to respondents in the former GDR, they clearly expressed the continuing effects of such historical differences, as explained by a government official in Saxony:

Yes, there is a big difference. When the GDR [the Democratic Republic of Germany] was in power, we had many more food inspectors than we do now. The Soviet government wanted to contain any crises and present a calm picture to the rest of the world, so that's why we had so much inspection. There is still a drive to have a high level of food safety inspection here. (Saxony_2013a)

Another Saxony official further emphasised this point by stating the differences in food law between the GDR era and today:

GDR law was possibly even more specific than it is now... food hygiene was very important. (Saxony_2013b)

The level of food safety coverage offered by central government appears to have been different before and after reunification. However, local expectation of food safety – the need for a high level reflective of one present during GDR times – is still apparent.

Variance across the Länder is not just restricted to historical differences between the former East and West of the country. Respondents from different Länder identified a series of normative, cultural and economic differences across Länder, irrespective of their status during the period of the segregation of Germany following the Second World War. Economic variances were quite straightforward, as there is an uneven distribution of wealth across Germany, with the traditionally wealthy Southern Länder of Baden-Württemberg and Bavaria having more economic clout than the “new” Länder, formerly of East Germany. This will have implications for the resources available for inspection, and would explain why wealthy Länder such as Bavaria and North Rhine Westphalia have specialist interdisciplinary organisations dealing with food/consumer safety. However, economic considerations have also been linked to the relative power that Länder have in standard setting and establishing best practice across Germany, as a respondent in Saxony made clear:

Standards are set by the western Länder, because they have more money and so have more power. (Saxony_2013a)

Cultural and historical differences between the Länder may also have an effect on the type of food safety expertise present in each Land. Some Länder may have certain food production operators which others don't. This can affect how food businesses are inspected and what types of food businesses a given Länder may prioritise. For example, in Saxony, the Länder authorities have a special focus on the consumer end of the food chain, such as restaurants, hospitals and kindergartens. One explanation returns to the distinction between east and west, as in the case of kindergartens, they offer lunch and dinner as opposed to in western Länder, according to a Saxony government official (Saxony_2013b). Another explanation is because Saxony does not have many large food producers or any significant large agricultural holdings. This is not something that is confined to differences between the east and west of the country, as a respondent from the Baden-Württemberg government made clear:

The large animal industry is in northern Germany, whereas in Baden-Württemberg you only have small animal holdings. There is a big difference to how you would approach a holding with maybe 30 to 40 animals, and one where you have thousands of animals. (BW_2013)

Local practices and the landscape of food businesses cause regulators in different Länder to prioritise in different ways. This suggests less uniformity across Germany as the makeup of food businesses, and the enforcement expertise required to regulate them, varies. However, far from compromising consistency, it was argued that this allowed for a useful range of expertise during Länder discussions:

The advantage of a federalised system is that we have 16 very competent people debating the issues. This will lead to more arguments, but they are important for coming to the right opinion. (Saxony_2013b)

An official from the BVL offered a further advantage of the federalised system:

Even though more time is needed to reach a decision across the Länder, the system does have the advantage that competent authorities are closer to the consumer.
(BVL_2013)

So even though a federalised system makes the decision-making process more drawn-out and complex, it allows for a diverse range of expertise that is more directly accountable to the regions represented than a centralised system can possibly claim to be. However, while the variation of expertise between the Länder support a fragmented system, how does competency across the Länder work? As discussed, the differing food business makeup across Germany can lead to different modes of enforcement. The AVV Rüb is deliberately vague in defining the level of expertise that is required within food safety inspection of FBOs, allowing for more specialist inspectors should an FBO warrant it. It does not clearly distinguish between a high-street grocery and a huge food processing factory that exports all over Germany and around the world. This has become a source of worry for the federal government:

Who should be in charge of inspection of a premises that is exporting not just to other Länder, but also outside of Germany? It should be the federal government. But the Länder would not agree to this as it reduces their power. (BMEL_2014b)

The federalist balance of power within Germany has, rather ironically, once again made it difficult for federal oversight to increase its purview over what could be classed as federal issues. However, although the Länder would reject such an increase in centralisation, depending on the makeup of FBOs within their authority, there has been a range of differing approaches to dealing with potential diversity within FBO size/specialisation. One Länder, North Rhine Westphalia, which has a range of large food businesses that do export internationally, has altered its approach to enforcement:

In North Rhine Westphalia, they have started organising multidisciplinary inspection teams for large food operators, so that they have the required expertise to properly inspect the establishment. It also deals with the difference in scale... where no longer do you ask one local food inspector to inspect the entire Nestlé factory.
(BMEL_2014b)

However, this system is not centrally organised, so each Länder can implement such an approach as it sees fit. Therefore, although there are multidisciplinary institutions in other Länder providing support (e.g. in Bavaria and Lower Saxony), such support can be to a differing extent or not present at all. This has implications for food moving across, as well as outside of, Germany, and explains the federal level's preference to bring inspection of large and complex food businesses under the auspices of a centralised unit or taskforce. A common retort from the Länder is that a rare and large-scale inspection conducted by a federal authority would not expose any shortcomings compared to more frequent local inspections, where the inspectors are aware of the makeup of the food business and the staff that run it. Regardless, in order for the responsibility for such types of inspection to be moved from the Länder to federal level, there would need to be constitutional change approved by the Länder themselves, and this would be highly unlikely.

Finally, and perhaps most significantly, there appears to be variation across Länder with regard to setting the level of food safety in each state. When a federal law exists that bans a food group, or process, then all Länder enforce the measure. However, when a federal law does not exist, variations between Länder begin to appear. Such a situation with nicotine in eggs was recounted by a respondent working for the Bavarian government:

We had some years ago nicotine in eggs in Lower Saxony. Here in Bavaria, you don't have that many egg producers. It's not allowed in eggs, so as soon as there is nicotine, we have the opinion that the eggs have to be withdrawn from the market. In Lower Saxony, they had millions of eggs with nicotine, and they did toxicology – they said [the levels of nicotine present are] not toxic, so they left the eggs on the market – because it was millions of Euros. Each Land takes the decision for their food operators. (Bavaria_2013a)

Here, differences in risk appetite, underpinned by competing scientific and political opinions, led to markedly different approaches in two Länder. This situation also underlines the great level of autonomy that exists at a Länder level, where no federal regulation dictates an outcome. The simple conclusion here is that, in the case of nicotine in eggs at the very least, there is a different expectation of safety.

A system like this, where the level of safety can be set differently in different parts of the country, will surely create difficulties in providing rationale behind enforcement actions. One observed outcome is for food businesses to play authorities off against one another (HR). One business might complain that it has been treated more harshly than another business that may be in a neighbouring town or village. Respondents from district authorities across Germany agreed that this was not an uncommon situation. The arbiter of such disputes, other than local authorities coordinating with one another, are the administrative courts. Different local authorities may have different forms to fill in, and different quality management systems in place, but they all must have clearly articulated legal arguments that take into account administrative law:

The logic must be the same because of the administrative court. So we close a premise, the owner of the premise can go to court and say “it wasn’t necessary to close, I would have done it [made the necessary changes] while I’m still operating”. Then the judge has to decide whether we did right or not. The legal explanation why we couldn’t do it in another way, must be on this form. (Stuttgart_2014)

With the high degree of autonomy of food safety enforcement throughout Germany, added weight is put on how an inspector’s actions are legally interpreted. Ensuring the legality of an inspector’s actions is of course nothing specific to Germany. However, legal considerations have a greater than expected harmonising influence across inspectors throughout a Land, and across the Länder.

However, it is not simply the enforcement action taken by an inspector, and the process by which he or she may reach a decision that shows a degree of variation. Different district authorities within the same Land can give different product information warnings from one another, much to the frustration of one respondent in the Bavarian government:

[It is] difficult as it can happen that one authority says, “yes, I want to inform the public about this product”, and another says, “no for me, it’s not dangerous enough, it’s only being sold some five times and I can prove that”. So, you have different opinions. (Bavaria_2013b)

Unless there is a specific federal law or Land law, district authorities have the autonomy to do as they see fit. The notion that in Germany, there is a clear distinction between safe and

not safe, may hold sway, but is entirely dependent on how one represents Germany. For if someone were to define Germany as a collection of autonomous regions, whether they be states or districts, they may all be practicing this clear distinction, but with the level of safety potentially set at different levels.

6.3.5 Information asymmetries

While respondents from different Länder accept that there is variation across the Länder, albeit to different extents, generating a formal picture of such variance is very difficult. For example, from the perspective of federal auditors, achieving this overall picture is dependent on each Länder agreeing to participate in an audit. The Länder aren't legally compelled to participate and there are numerous instances where federal audits have either decided, or have resigned themselves to, collect information from fewer than the full complement of Länder authorities. As the federal auditor for agriculture and food safety made clear:

We do not have the authority to force Länder to contribute to our audits, it's entirely voluntary. German Basic Law ensures this autonomy of action.
(Bundesrechnungshof_2014)

It is not just the federal auditors who have to deal with informational deficiencies – federal level authorities also suffer with information asymmetries. At the most fundamental level, BMEL is quite unaware of the number of food inspectors working within Germany. As one BMEL director put it:

I have no idea how many food inspectors are working for Länder authorities; I doubt even each individual Länder knows [how many inspectors work within its jurisdiction]. (BMEL_2014b)

Indeed, respondents from nearly all the Länder interviewed stated that there were other Länder who were not aware of such basic information (although none of the respondents admitted this was the case within their authority). For example, one respondent in Bavaria stated:

I'm aware of at least three other Länder authorities that lack rigorous audit mechanisms. Clearly, they are unable to accurately reflect the number of inspectors throughout their local districts and what exactly those inspectors are doing.

(Bavaria_2013a)

Such a state of affairs was reflected in Baden-Württemberg:

There are Länder where they do not know how many people are working in the local controls. (BW_2013)

So, not only is it challenging to compare food safety systems between different Länder, it may be just as difficult at a district level to assess differences in enforcement practices. For example, in Baden-Württemberg, local authorities have their own Quality Management Systems (QMS), and different procedural forms:

Local authorities implement their own [Quality Management System], so it is difficult to audit across districts. When it comes to closing a premise, because it's dirty and needs to be repaired, we have a different form that we fill in than our neighbours. (Stuttgart_2014)

Not only can the systems be different within a single Land, inspector approaches to food safety can vary quite substantially as an inspector from Stuttgart recounts:

When I go to the Black Forest, they are more relaxed about the level of food hygiene. Perhaps because it is close to the French border, they inspect more like French inspectors! (Stuttgart_2014)

Producing an overall picture of a Land can prove problematic, as variation right down at a local level, and the autonomy that allows it, could lead to differing levels of food safety expectations, as well as differing food enforcement practices.

6.4 Conclusion

This chapter concludes that, in the main, the UK offers a relatively consistent risk-based approach to food safety enforcement. The German approach by contrast is significantly different to that of the UK, as its enforcement regime is signified by the presence of multiple risk regimes loosely tied together by federal facilitation of best practices, and the implementation of EU regulation.

Table 2. Comparison of key factors shaping application of risk-based approaches to local food safety enforcement in the UK and Germany.

	UK	Germany
Harmonisation of enforcement	High	Low
Centralisation of enforcement oversight	High	Low
Regional variation in food safety expectations	Low	High
Juridification of food safety regime	Low	High
Levels of corporatism	Low	High

Comparison of local food safety enforcement within the two countries show significant variance in enforcement regimes. Food safety inspectors in both countries talked about the issue of constrained resources, and the appeal of risk-based approaches as an organisational logic for distributing these resources. However, as table 2 indicates, there are some fundamental differences in the organisation of enforcement practices, as well as variance in national and regional contexts.

While the experience of Great Yarmouth is the exception that proves the rule, there is a relatively high degree of harmonisation across the enforcement of standards in the UK. The Food Law Code of Practice, coupled with supporting documents provides a detailed manual for enforcement actions. The FSA, which is responsible for producing the Code of Practice, maintains oversight of local authorities through a series of audits. A high degree of centralisation is evidenced by empirical evidence gathered on the subject of accountability – reputational risk tends to be of much greater concern to the FSA than local authorities, with many claiming that they did not lose any reputational cache following the BSE crisis.

The situation in Germany is, however, quite the reverse, with significant informational asymmetries that exist between national competent authorities and regional inspectors. Such asymmetries are compounded by Länder autonomy in applying enforcement standards and pronounced regional variance in food safety expectations. While Germany has made significant progress in harmonising enforcement approaches by organising Länder committees, as well as the coordinating work of the BVL, interviews with respondents revealed that there are significant differences between, and even within, the Länder. One major difference concerned setting the acceptable level of risk that should be pursued by regulatory action, with evidence indicating historical path dependencies, as well as varying economic and geopolitical makeups of the different Länder. This has implications for the application of a unified EU risk regime across Germany, as there are different expectations of safety, but the ability to measure those differences is challenging. FVO audits of specific Länder will not necessarily reveal a representative sample of enforcement practices across Germany. In fact, even federal auditing of local enforcement practices is difficult, as there exists substantial informational asymmetries between the two levels

Lower levels of central harmonisation within Germany has led to the increased importance of the legal system within the country, as administrative and constitutional courts act as the final arbiter of what constitutes as permissible within the varied regulatory landscape. The overriding role that EU regulations is absolutely crucial here, as the EU regime imposes harmonisation that has not been achieved through national regulation alone (whether wilfully or not). Examples cited within the interviews with food safety respondents illustrate this, as the implementation of EU official controls and hygiene packages almost ground enforcement to a halt until clear clarification of the new rules was provided. Within the UK, EHO experience of the need to revert to the courts is quite different. Indeed, there has been a developing mentality within local authorities that the fewer cases that need to go to court, the better, albeit largely due to monetary considerations. Here, juridification is less of a phenomenon as the courts aren't required to provide harmonising impetus due to the presence of strong central regulatory oversight.

Finally, as was identified in chapter 4, the organisation of interest groups within the operation of enforcement has important consequences as consensus within Germany has to be drawn from a range of important professional interest groups. In the UK, this is not as clearly evident, leading to EHOs giving mixed messages with regard to the extent to which they feel their profession has a bearing on food safety regulation. However, it is the role of industry

within the corporatist organisation of German food safety regulation, which is of special note here. As industry associations must train and insure food businesses within Germany, evidence gathered for this thesis indicates that German food safety inspectors place far more emphasis on assessing and scoring the establishment, than their UK counterparts. For in the UK, without the same corporatist framework, inspectors told this author that their most important function is not the scoring of businesses, but providing education. The UK experience would ally more with a risk-based approach as the use discussion and education is symptomatic of soft compliance, whereas in Germany there is more of a tendency towards command and control, especially reflected in the case of Baden-Wurttemberg, where until recently a specialist branch of the police force was involved in inspection.

The evidence gathered in this chapter would suggest that the UK has been able to more easily role out a universal risk-based standard of food safety enforcement. This has been aided by a more hierarchical implementation of the regulatory landscape leading to less fragmentation, signified by less dependence on juridification or corporatist solutions to regulatory problems, and the role of soft compliance in dealing with food businesses.

However, it should be noted that in the UK, the rollout of risk-based approaches is not without difficulty. Disagreement over the role that confidence in management plays in an inspection shows the discomfort that some EHOs feel in focusing on businesses checks and balances as a proxy to risk, rather than focusing on the hazardous activities themselves. The Primary Authority scheme had revealed further tensions, as part of an EHOs inspection had been absolved to a central authority, despite the variations in management practices between different chains of the same business. Furthermore, Primary Authority emphasised the importance of allocating enforcement resource based upon the level of compliance of internal business audit systems, moving enforcement further away from regulating hazard.

Chapter 7 – Risk and food hygiene barometers

7.1 Introduction

Food hygiene barometers are symptomatic of an evolution in many countries, focusing on increasing citizen participation within regulatory apparatus that was once only the domain of the State. The narrative that has been provided to elucidate this shift has spoken of the move from subjects (how can you serve your country) to citizens and consumers (how can your country serve you). “The public”, despite its singular taxonomy, does not relay one homogenous mass, but a highly intricate and complex web of demographics. Its changing status, coupled with attempts by state and non-state actors to engage with it, has led to the creation of sound bites that are political gold dust, such as “empowered citizens”, “engaged voters” and “informed consumers”.

But how exactly can food hygiene barometers inform, engage and empower consumers? Consumers are informed as they are exposed to the results of food hygiene inspections. They become more engaged as food safety inspectors convey their assessments in a way that the public can utilise, informing their choice of food business. Finally, consumers are empowered as they can exert pressure on food businesses by “voting with their feet”. Food businesses will not want to have negative assessments of their food hygiene practices published for fear of their customers deserting them and choosing a more hygienic alternative.

In theory, food hygiene barometers offer benefits beyond consumer engagement. If consumers choose establishments with high hygiene ratings, and vote with their feet, lower scoring establishments should be incentivised to improve their hygiene. The outcome should be a decrease in the incidence of foodborne infections.

However, when trying to assess the efficacy of these barometers, whether that be through measuring food borne infection, greater public understanding or behaviour modification in businesses, the evidence has been inconclusive. This chapter will argue that even though these barometers do indeed increase both public and business participation, they can divert attention from one of the main reasons they have come to exist – to reduce the inherent level of risk within a food business.

7.2 The UK Food Hygiene Rating Scheme – full steam ahead?

The use of food hygiene barometers in the UK is the product of a move away from conventional regulatory enforcement norms. Such conventional wisdom is characterised by inspectors using their statutory power to impose legal sanctions on establishments that have broken the law. Only a couple of decades or so previously, this would have been conducted in private with food businesses, with the public only aware of inspection outcomes if severe enforcement actions were taken, such as taking an FBO to court, or closing the business down. Indeed, since the first government hygiene inspectors were appointed at the turn of the 20th century, public knowledge of their inspections was greatly limited, if not non-existent. This level of public opacity endured throughout the 20th century, with what appeared to be an inalienable right to commercial sensitivity trumping any allowances for public scrutiny. There was some movement towards increasing public oversight, such as the MAFF surveillance of British supermarkets, beginning in the 1980s, but examples such as this were viewed as exceptions to the rule. Towards the end of the 20th century, local authorities were beginning to think about how hazard scores generated for food business inspections might be conveyed to the public. For example, in 1997 Norwich City Council piloted a public display of food hygiene ratings: the first example of linking an inspection's hazard scores with a "Scores on the Doors" approach. However, the pilot fell afoul of the council's legal department, with one of the pilot's authors suggesting a lack of appetite to start publishing previously private information:

It was clear that the objection was more indicative of a widely-held suspicion afforded to award schemes at the time and in particular the voluntary disclosure of previously hidden council information in the express hope of changing attitudes. (Stanton, Burton & Gooding, 2008).



Figure 5. Example of a Scores on the Doors rating

It was not until the seismic shift created as a result of the BSE crisis, coupled with the passing into law of the Freedom of Information Act, that things began to change. The Labour government at the beginning of the 21st century urgently sought to repair the UK food safety regime's reputation, after it lay in tatters following the BSE crisis. As discussed in Chapter 4, one of the recommendations put forward by the James Report was to have an independent government organisation that would represent consumer rights and interests. And so, the need to put consumers first was at the core of the statute that led to the creation of the Food Standards Agency. This was in stark contrast to the previous status quo, where business interests and commercial sensitivity were the order of the day for regulatory action and oversight. This new way of doing things was supported and enhanced by the introduction of the Freedom of Information Act in 2000, which gave the public the right to access information held by public offices. The citizen had been placed very much front and centre during this latest stage of regulatory evolution. It was not long until this new paradigm of explicitly protecting consumer interests and delivering freedom of information led to a renewed effort to test pilot studies of food hygiene barometers at a UK local level. This time, these pilot schemes did not cause local authority legal departments to run for cover. Norwich, building on its previous attempt, led the way in 2005 with the Norwich Safer Food Award – based upon the FSA's risk-scoring protocols found in the Food Hygiene Inspection Rating Scheme. As other local authorities became involved, the pilots were loosely brought together under a previously maintained "Scores on the Doors" scheme. Following evaluation of

Scores on the Doors by the FSA in 2008, the government department opted to take central responsibility for a coordinated national barometer, and this paved the way for the Food Hygiene Rating Scheme (FHRS), introduced in 2011.

Now that the FHRS is universally used throughout local authorities in England, Wales and Northern Ireland, it has marked a paradigmatic shift in how regulatory enforcement is carried out. While the inspections themselves are still conducted in private, the outcomes are much more transparent, with FBOs publicly scored on their level of compliance. This is significant, as we move from a context where the public was largely unaware of the outcome of FBO inspections, to one where the public itself acts as a lever for changing behaviours in food businesses.

7.3 How does the FHRS fit into existing practices?

The way in which the FHRS reports findings by an Environmental Health Officer has implications for the enforcement action an officer might take, as well as behaviour change in the business and the consumer. To summarise, an EHO's report is distilled into three main categories: structural soundness, food handling knowledge and confidence in management – that combine to determine the overall hygiene score awarded. The scheme is intended to reflect the risk-based approach to enforcement, utilised by principle authorities, as per the European Commission's regulation on official controls (882/2004). However, the report is not a complete reflection of an EHO's overall inspection and categorisation under Annex 5 of the Food Law Code of Practice. The key difference here is that the Code of Practice factors in the intended use of the FBO and the population it serves (e.g. hospital canteens have a higher risk ranking because patients are categorised as a vulnerable group), as well as categorising FBOs from high-risk category A, through to low risk category E. The FHRS categorises FBOs with numbers 0 through to 5, reflecting the level of compliance. Therefore, there can be significant discrepancy between the two different scoring schemes – a hospital canteen could be found to be fully compliant under the FHRS (scoring a 5), yet could be classified as being at greater risk (due to the higher vulnerability of patient groups) and therefore score lower on the Annex 5 calculation.

So, on a fundamental level, there are some clear differences between the FHRS and the Annex 5 calculation it is based upon. The question here is to what extent does the FHRS fit smoothly into a regulatory approach signified by the Annex 5 risk rating? Clearly, the FHRS serves a much wider audience, as public oversight is brought to bear on inspection outcomes. To what extent does such oversight affect the work of EHOs, whose work is now thrust into the limelight? Can such an instance of “opening up” at least part of a regulatory regime to public scrutiny have important implications for the core aspects of enforcement? Specifically, does the FHRS both reflect and preserve the risk-based approach to food safety inspection, as intended?

7.4 The intention of the FHRS

The premise of the FHRS, and the Scores on the Doors schemes that preceded it, is a relatively straightforward one. It is designed to ensure that FBOs maintain a high level of food hygiene. The assumption here is that, with scores publicly available, a member of the public will take her business elsewhere if she sees that an establishment has a poor score. Not wishing to lose the trust and business of the consumer, FBOs are incentivised to ensure that they are fully compliant with the food hygiene regulations set. At the same time, the consumer can make a more informed decision on which FBO to visit based upon the hygiene information released. This could be viewed as a form of libertarian paternalism, as it leaves the decision of which establishment to choose in the hands of the consumer, whilst at the same time influencing the consumer’s decision-making process. The consumer is “empowered” by making a more informed decision without the need for overt regulation dictating how such decisions should be taken.



Figure 6. Example of an FHRS rating

7.5 The efficacy of the FHRS

The FHRS should therefore help consumers reduce the level of food hygiene risks they are exposed to whilst incentivising FBOs to manage and mitigate those risks. However, there is relatively little data to suggest the efficacy of such a scheme and whether it does improve levels of food safety. Indeed, there is some debate as to what the primary aim of the FHRS is – to incentivise businesses, empower the public, or both. As the FHRS has only been running since 2012, it is hard to judge whether the scheme has been seen as a success by any of the yardsticks set. As mentioned, there have been previous pilot schemes in the UK, as well as established schemes outside of the UK. High profile overseas examples include the Smiley scheme in Denmark, the traffic light scheme in Toronto and the letter grading in California. There have been a few studies that have measured the performance of these schemes. But with differing views on what constitutes good performance and the use of different barometers in different regulatory environments, comparison proves difficult. One common measure of success has been trying to infer whether food hygiene barometers have reduced the level of food borne illness, or more specifically, incidents of campylobacter. Drawing across these findings, the outcomes are inconclusive, with some suggesting real impact of such a scheme (Food Standards Agency 2015), while others state that there is very little, if any, impact (Simon et al. 2005). Despite having conducted studies on the Scores on the Doors schemes, the FSA still readily admits that it is difficult to currently measure the efficacy of the FHRS:

The FHRS has only been running since 2012, so it's hard to measure its exact impact. We're waiting until there's full uptake of the scheme across all local authorities before we can get a truly representative view. (FSA_2013e)

Primary authorities themselves appear to be divided on the current and future impact of the scheme. Some EHOs are of the belief that the FHRS will have a substantial impact once the scheme has properly embedded across all local authorities:

When there is complete national coverage, they can, and are starting to, produce education, adverts, billboards to educate the public about the scheme. (Brighton & Hove_2014)

Whereas other EHOs have claimed that the scheme drew more interest when it was first introduced, due to its novelty factor, but its impact has been slowly dwindling since:

Once the initial introduction died down, it's not as effective as it was. (Horsham_2014)

Finally, some EHOs are not convinced either way, and point to the possible impact on businesses as well as the public:

Another huge debate is what people in the street think about them [FHRS scores]. Are they really influenced by the stickers they see in the windows and the information they've seen on the websites? The FSA would argue very passionately that the public are interested in this stuff... You could argue that the public are motivated – whether businesses are motivated is another matter (Huntingdonshire_2014)

This is key to the effectiveness of the FHRS, as both the public and food businesses need to be engaged with the process. Should businesses not show any motivation, clearly there would be no upsurge in compliance to be expected from a functioning scheme. Likewise, should the public not be influenced by the stickers they see on the street, this could also disincentive businesses to drive up compliance.

7.6 Does the FHRS change enforcement practices?

Whilst there is limited data indicating the effectiveness of the FHRS and its effects on FBO compliance and public awareness, there is even less data pointing to the effect such a scheme has on the EHOs and the inspections they conduct. The outcomes of such food barometers may be directed at the consumer and FBOs, but do they affect the risk-based enforcement regime? Interviews with EHOs across the UK indicate that the FHRS could have a profound effect on their work.

7.6.1 Changing the approach to objectivity

The objective calculation of an establishment's score through an inspection that is, in many ways, subjective, can significantly affect inspection frequencies and enforcement outcomes, dependent upon the individual EHO. While the scoring criteria is quite robust (e.g. checking that refrigerators are operating at the correct temperature), other aspects of the assessment made by an EHO can be open to interpretation (e.g. does the inspector have confidence in the management of the FBO?).

However, the introduction of the FHRS may have taken a little subjectivity away from an EHO's inspection. As one EHO put it:

Previously, I've known inspectors who have slightly amended their Annex 5 score to move the business to a different category [of inspection frequency]. This is because they know that a new owner is coming in, or the chef is leaving soon, or that the inspection fell on a particularly good or bad day for the business. (Rother and Wealden_2014)

With the FHRS, a suitable bump in direction for the Annex 5 score would have a corresponding effect on the FHRS value. Whereas businesses might not have minded a change in inspection frequencies before public scoring, it is much harder to defend a score when it is being publicly posted and the business wants to achieve the highest score possible.

7.6.2 Changing the approach to consistency

However, the FHRS may have had a somewhat unintended consequence in terms of driving up consistency of scoring. Consistency appears to have been an ongoing issue for EHO inspections:

There's a lot of consistency issues over scoring, with interpretation, and despite every effort made by the FSA and local county liaison groups, there are still managers who have quite differing views on how to score... I think a lot of EHOs are too black and white. (Rother and Wealden_2014)

As the respondent states, the role of food safety managers within EHO inspection teams is to ensure consistency across inspectors. However, individual EHOs may have different methods of forming working relationships with FBOs and this has had repercussions on how individual EHOs apply both Annex 5 scoring criteria.

As FHRS scores are publicly available, this has led to more discussion amongst inspectors on scoring:

Yes, I suppose [the FHRS] has led to more discussion about the scoring. EHOs wouldn't want to look out of place with their colleagues. (Huntingdonshire_2014)

The very public nature of the FHRS seems to have led to some EHOs worrying about being seen as the odd one out when it comes to assessing businesses. This may contribute to increasing levels of consistency not only in the FHRS scoring, but in overall food hygiene inspection practices due to the close links between the Annex 5 calculation and the FHRS.

7.6.3 Changing the approach to risk-based enforcement

The FHRS may well already be having an unintended impact on the risk-based nature of EHO inspections. As the comment below indicates, every single EHO respondent interviewed for this thesis stressed the importance of proportionality and prioritisation with regard to risk-based approaches:

*I think it's about prioritising things rather than making decisions based on risk ...
We've [EHOs] had it drummed into us that our actions must be proportionate to risk.
That even begins with the premises we go to and how often we go to them.*
(Huntingdonshire_2014)

Indeed, some EHOs saw proportionality as an essential pillar to the enforcement activity they carry out:

We pride ourselves on being proportionate and having scientific evidence that is risk-based. (Horsham_2014)

Common sense dictates that EHOs dedicate more of their time inspecting and educating FBOs that consistently fall below hygiene requirements, as opposed to those that are broadly or entirely compliant. However, it can be argued that the transparency drive that has led to the creation of the FHRS could affect this basic tenant of proportionality.

With the range of underlying impediments to food businesses being able to achieve compliance with food hygiene standards (see Chapter 6), it is easy to see why EHOs argue that a proportional approach is needed, as part of a risk-based system. Therefore, one might assume that an enforcement system would be set up to ensure that EHOs were spending more time with the less compliant FBOs. However, the FHRS could lead to quite a different outcome. Due to the publication of food hygiene scores, certain FBOs will be eager to show their customers they are at full compliance (5 out of 5 on the FHRS scoring scheme). Traditionally, these will be companies who have consistently tried to achieve full compliance previously, and who would have been broadly compliant (3 out of 5) or better. As the FBOs have the right to appeal or request a revisit under the FHRS scheme, this can prove to be problematic for EHO inspectors and their attempt to provide proportional enforcement.

Take, for example, an establishment that scores 4 out of 5. Under the terminology of the FHRS, this establishment is rated as “Good”, which equates to a good level of compliance, with only minor infringements of food hygiene regulations. Under Annex 5 of the Food Law Code of Practice, such a compliant business could come under category E, requiring “A programme of alternative enforcement strategies or interventions every three years” (FSA

2014). This could lead to a situation whereby an establishment that should be inspected no more than once every three years, is in fact reinspected just three months after its initial inspection, due to a revisit request.

With the added burden of re-inspections, it can be argued that the pressures placed upon local authorities have been increased. And if it transpires that local authorities are having to dedicate more time and resources to FBOs that are largely compliant, does this not affect the proportionality of a risk-based enforcement regime?

The full extent of this issue is difficult to gauge. Some EHOs have suggested that the impact of revisits is relatively small as there haven't been many requests following the introduction of the FHRS scheme:

Currently, maybe because the FHRS is yet to take off, the number of requests for revisit is low. (Brighton & Hove_2014)

However, the FHRS could be the victim of its own success, should it become an increasingly popular tool. One EHO stated that with the FHRS having been fully rolled out, coupled with the FSA's intention to increase its advertising, FBOs will show more interest in getting high hygiene scores:

I think if the FHRS gets more popular, business will increasingly take the system more seriously and there will be more and more requests for revisits. If the public takes note of these scores, then there will be plenty of businesses who will suddenly want a 5. (Rother and Wealden_2014)

Therefore, it appears that the popularity of the FHRS could be proportional to the number of revisits required. If businesses are worried that the public may start to actively and consistently use the FHRS scores as a means of choosing their establishments, it could be assumed that there would be increased pressure on FBOs to make sure they score as highly as possible, increasing the demand for revisits. This presents the problem of inspectors spending an inordinate amount of time in low risk establishments. Could the FHRS, as a transparency measure, serve as an example of how increased transparency could be inversely proportional to risk-based dynamics? The FSA is currently working towards measures to reduce the

increased workload brought about by FHRS revisits, with emphasis put on the fact that a revisit does not need to be as thorough as the original inspection, especially if there were only minor infringements. However, this does not sit well with some EHOs as it amounts to an inspection “lite”, no matter if it is a revisit, and runs contrary to the possibility that the situation in an FBO might have substantially changed, or that the EHO feels greater accountability with a far less thorough inspection. As one EHO put it:

I wouldn't want to feel responsible for making a visit, whether it be an initial inspection or a revisit, and cutting corners. The situation in FBOs can quickly change, so an inspection is an inspection. (Rother and Wealden_2014)

7.6.4 Constrained resources

One of the key concerns for EHOs interviewed was constrained resources. It does not appear unusual for a local authority to fail to meet its inspection quota as set out by Annex 5:

It only happened recently, when another local authority, I think it was Torbay, came out and said “really sorry, but we don't have enough EHOs to meet our Annex 5 requirements.” As a result, the local authority stated that any FBO that had already attained a 5 out of 5 FHRS score would not be reinspected for the next year. (Horsham_2014)

The public scrutiny this brings, which wouldn't have existed prior to a transparency scheme, adds pressure to the local authority. With the potential increase in revisits, brought about by FHRS reinspections, local authorities are increasingly stating that they cannot fulfil their allocated quota of inspections. As local authorities divert their resources to businesses that aren't fully compliant, more instances like the one alluded to above will occur, with FHRS rated 5 businesses waiting increasingly long periods of time to be reinspected. While there has understandably been a lot of debate around establishments that rate poorly but then wish to quickly improve for a quick reinspection, what about FHRS rated 5 premises that know they do not face inspection for a greater length of time, as in the case of Torbay?

7.6.5 Implications for local authority inspection

Whilst there has been a lot of discussion about the efficacy of the FHRS, there has been very little analysis of its effect on the pre-existing regulatory regime. Discussion with EHOs has revealed some important areas where the FHRS has had such an impact. It may be responsible for making inspections more consistent and objective (or at least less subjective). However, the public nature of the FHRS likely places further pressure on the increasingly constrained resources of local authorities, leaving some FHRS highly rated establishments being inspected less frequently than the risk scoring of Annex 5, to focus on poorer performers. However, it is the fundamental effect that the FHRS has on the risk-based nature of inspections that could have the most profound impact, as EHOs try to balance out reinspections of aspiring businesses that have fallen a little below the mark of full compliance, with poorly performing businesses in need of a great deal of support and education.

7.7 German food hygiene barometers

Food hygiene barometers within the German context, despite the introduction of promising local systems, have largely failed. As introduced in Chapter 2, Germany's experience of attempting to introduce these systems has been fraught with problems, which include a complex mix of political, judicial and normative aspects. As the development of food safety enforcement in Germany has largely been one of local led, Länder responsibility, the introduction of barometers has brought the fragmented nature of Germany's political system into sharp focus.

7.8 A false dawn for German barometers?

Following on from Ilse Aigner's (the then minister for Agriculture, Nutrition and Consumer protection) refusal to write the public availability of food hygiene scores into law, due to a lack of unanimous support from Germany's Länder (Bavaria rejected the proposal), there have been a few instances of pilot projects occurring in various German cities. Perhaps the most established pilot project was in the Pankow district of Berlin (the "Smiley Projekt"), where a range of smiley faces were posted online (and voluntarily in store) that reflected the number of assigned minus points that an FBO accrued during a food safety inspection (for an

example, see figure 7). The cities of Duisburg and Bielefeld (both in North Rhine Westphalia) also implemented similar pilot projects, making food hygiene inspections publicly available (for an example, see figure 8).

Measuring the efficacy of the German pilot projects has proved difficult. As Pankow and the pilots in North Rhine Westphalia use different systems, exact comparison isn't possible. Furthermore, the systems in North Rhine Westphalia have gone through several different iterations (and at last count settled on a traffic light system, *Gastro Ampel*), in order to appease businesses and their Länder administrations. In Pankow, the initiative appears to have increased business compliance:

Before the smiley system, no matter how many times you visited a business, you would constantly be giving the same instructions. The business would agree to them and might possibly implement changes, albeit briefly. As soon as you came back round, everything would return to its original state. With the barometer, businesses are now implementing changes permanently, as they want to score highly on the smiley system. (Pankow_2013)

Pankow also benefited from the fact that it was one of the first pilot projects testing publicising food ratings. Surveys showing that the public was predominantly in favour of publicising these scores led to political capital for Pankow and increased media attention:

Before we introduced the smiley scheme, we conducted a survey that stated 95% of Pankow's population would like to see our inspections made public. Because this was an original idea in Germany, there was plenty of press attention and our local politicians wanted to be seen as being on board. As a result, our budget was raised for food inspection and we were able to recruit more food inspectors. (Pankow_2013)

So, not only was the smiley system improving rates of compliance, with an assumption that consumers were being exposed to fewer food risks, the system was also able to focus public and media attention on food safety, resulting in politicians providing increased funding and support.

At this point, it could be argued that the Pankow project was a great success story, championing food hygiene barometers to the rest of Germany, which no doubt would follow suit. However, by April 2014, the constitutional court ruled that it was illegal to publish the hygiene scores of businesses within the Federal Republic of Germany. The scheme in Pankow was shut down, and the schemes in Duisberg and Bielefeld are under serious threat. The sudden, or imminent, cessation of such schemes is an indicator of the challenges Germany faces not only in producing harmonised control mechanisms across the 16 Länder, but also the legal minefield that is a direct result of federal constitutional arrangements.

The next section will provide a brief historical background to the adoption of food hygiene barometers in Germany.

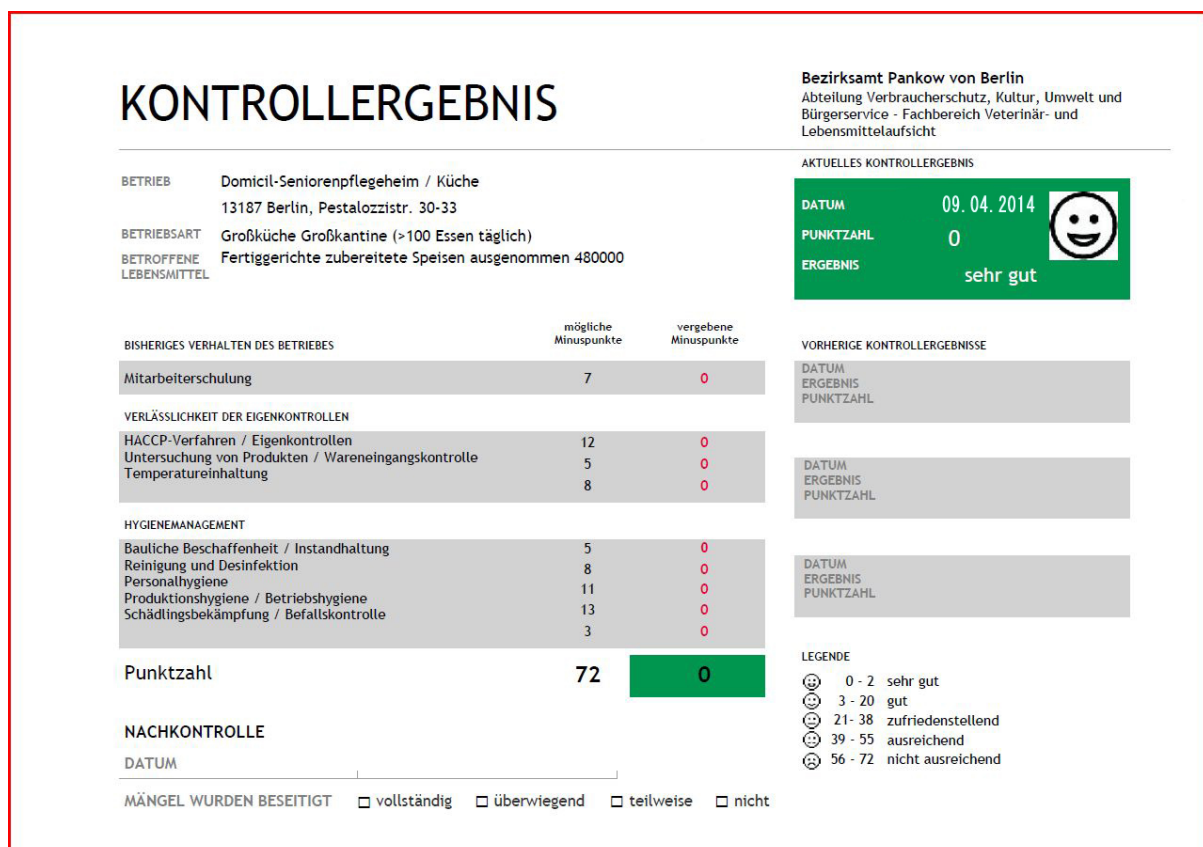


Figure 7. Example of Pankow's barometer

7.8.1 Consumer interests

The political narrative in the former West Germany, as well as the reunified Germany after 1990, placed consumer interests on a higher pedestal. Historically, there has been a long tradition in protecting consumer interests. As described in Chapter 2, Germany has become

synonymous with a system of corporatism that goes beyond, but is signified by, Bismarck's social security legislation of the 1880s. Consumer groups have therefore long enjoyed an important role in many sectors of public administration. Germany's consensus driven politics, in order to historically appease a union of influential city states, and then Länder, has facilitated the rise of citizen associations and NGOs. Consumer interests have been represented in fields from health to insurance, banking to workplace health and safety. John F Kennedy's proclamation of the four fundamental rights for the consumer, as well as the rise of new social movements in the 1960s and 1970s, further bolstered consumer organisations in Europe, and notably Germany. In 1971, the government of Willy Brandt published Germany's first paper on consumer policy, as well as establishing a standing committee for consumer affairs. Developments in the European Economic Community reflected Kennedy's earlier attestation, when in 1975 the European Commission proclaimed its own five fundamental rights for consumer protection. Consumer protection and rights were apparent when, in 2001, the then Ministry for Consumer Affairs, Food and Agriculture was established. Consumer interests have become so important to the German state that the very taxonomy of German government has changed to explicitly accommodate them.



Figure 8. Two examples of Duisburg's barometer – green is “requirements fulfilled”, yellow “partially met requirements” and red “requirements inadequately met”.

This begs the question that if consumers have been richly represented at both a non-governmental and governmental level, surely a public information system such as a food hygiene barometer would be welcomed? Surely a tool that empowers consumer decision-making, and allows the public to peer into the apparatus of enforcement would work within a German context? Here we have the first significant roadblock to the use of barometers in Germany – the classification of the German consumer. Based on German case law, it has been argued that German consumers are, for the purposes of consumer protection rather naïve and unaware of the dangers that face them. Dausen (1998) makes this clear when he states, “German consumers are not really like the image that the German courts present. The portrait of a helpless, debilitated, immature creature who is in need of protection so as not to be led astray by advertising is not accurate.” Emmerich echoed this view (ibid.) and mockingly writes, “Basically the helpless consumer on the verge of debility, who is immature and needs extensive care, who has to be protected against the slightest danger”. Finally, Möllering (ibid.) defined the legal conception of the German consumer as a “pitiful being at the lower end of the intelligence spectrum”. Dausen compares this image with one that has been presented in the European Court of Justice, where the consumer is perceived to be bright, attentive, and capable of understanding and learning. This contrast would suggest a more hierarchical approach to consumer protection in Germany, as opposed to the individualistic one presented in the European Court of Justice. It is not for the German consumer to make an assessment of the risks that lie within a food business; the state should be guaranteeing their safety.

7.8.2 Safety and precaution

Not only are consumers historically seen as the appropriate actors to assess risks, but barometers that seek to convey a range of risk integers may also fall foul of the German normative approach to precaution. Enshrined within the German constitution is the right to safety for all German citizens as well as the freedom to trade for German businesses. The right to safety is what underpins Germany’s principle of *Vorsorge* and has historically been critical to debates surrounding the dichotomy of safe/unsafe. The argument here is that food hygiene barometers will fail because they point consumers to the grey area between safe and unsafe. The difficulty, according to the German courts, is that measuring the compliance of a food business doesn’t necessarily correlate with impact on public health. While the German

constitution protects against *koerperliche Unversehrtheit* (injurious to health), compliance scores cannot be used as a suitable indicator. Instead, only concrete offences can be communicated, and this would appear to correlate with the German reliance on safe/unsafe, showing that the courts still rely on the presence of certainty when ruling against food business owners.

From a German perspective, these ratings are interesting because they show a range of possible outcomes of inspection. In the case of Pankow, this range includes “not sufficient”, “sufficient”, “satisfactory”, “good” and “very good” as explanatory descriptors of the hygiene inspection. At first glance, this runs against the German precautionary principle of *Vorsorge*. Either the food business is safe for a consumer to purchase and/or consume food in or it is not. Such intolerance to risks means that either the FBO complies with German food law and can remain open, or does not and should be closed. Such barometers seemed to indicate the potential shift in German attitudes to the tolerability of risk. As one civil servant for the Pankow government commented:

If anything the public has shown great support for such a scheme. By having different levels of compliance, we are only reflecting what already occurs [with inspection frequencies]. Considering before we introduced the scheme a third of food businesses in Pankow were rated as not satisfactory, this public scheme drives them up the compliance table... I think the public sees that. (Pankow_2013)




The private consultancy behind the Food Hygiene Rating Scheme in the UK, which has also worked with German pilot projects, feels that the German safe/unsafe dichotomy is an artificial one:

It's certainly not a reason for why these control schemes haven't been rolled out in Germany. All they're supposed to do is reflect what already goes on within inspection; there's always been an acceptance that different FBOs have different levels of compliance.

Indeed, these food barometers might be an indicator of Germany's softening stance to the tolerability of risk. The BfR, for example, have rolled out a “Risk Profile” (see below), a publicly available risk matrix that indicates to the consumer the level of concern and caution

that the consumer might want to take following a risk assessment released by the agency. Amongst other factors, it explicitly states the probability and severity of health impairment along an integer scale. With regard to probability of health impairment, the scale consists of “practically non-existent”, “unlikely”, “possible”, “likely” and “certain”, whereas severity of health impairment includes “no impairment”, “slight impairment”, “moderately severe impairment” and “severe impairment”. Where would a contaminant sit on a tolerability scale if the probability was deemed to be “possible”, the severity health “slight impairment” and the informative value of the available data “medium”? The uncertainty over the level of risk would surely run afoul of Germany’s entrenched view of safe/unsafe. However, a director at the BfR refuted this:

It’s a matter of providing enough information to the public. It took us two years to construct this risk profile and we have found that as long as you provide the public with all the information that is required to make an informed decision, then there isn’t the need to put across a basic message of “it’s safe or not safe”. (BfR_2014)

 BfR risk profile: Health assessment of chlorate residues in food Opinion No. 028/2014				
A Who is affected	General population Children, persons with hypothyroidism or iodine deficiency  			
B Probability of health impairment resulting from Chlorate residues in food	Practically non-existent	Unlikely	Possible	Likely Certain
C Severity of health impairments resulting from chlorate residues in food	No impairment	Slight impairment [reversible]	Moderately severe impairment [reversible/irreversible]	Severe impairment [reversible/irreversible]
D Informative value of the available data	High: Essential data are available and free of contradictions	Medium: Some essential data missing or contradictory	Low: Large amounts of essential data missing or contradictory	
E Controllability by consumers [1]	Control not necessary	Controllable by taking precautionary measures	Controllable by refraining from consumption	Not controllable

Dark blue shaded fields designate the characteristics of the risk assessed in this opinion (more detailed information on this can be found in the text of the opinion).

Figure 9. Example of part of the BfR's Risk Profile, looking at the health assessment of chlorate residues in food

Each risk profile that the BfR releases is accompanied by its full scientific opinion. However, it could be argued that the Risk Profile is not measuring outcomes. After all, it is not the responsibility of the BfR to make management decisions. This falls to the BVL and BMELV, the Risk Profile is simply advisory in capacity. If, for example, a contaminant is not proven to

be entirely safe, no matter if it scores low on the Risk Profile, it could still be expected to be regulated. Indeed, this has caused a certain degree of frustration within federal risk management institutions, as a director in BMELV made clear:

Germany is the most precautionary country in Europe. It is very hard to be risk-based because if anything is found wrong, we are expected to regulate it. (BMEL_2014b)

However, the food hygiene barometers go one step further than the BfR's Risk Profile. While the public are left to make their own call on whether to visit the FBO in question, the barometer has already reflected the outcome of the food safety inspector's visit. Within Pankow, an FBO could score "not sufficient", indicating that it has major compliance issues, but it is still open – the inspection frequency will have been increased accordingly and a warning may have been issued, but customers could still frequent the establishment, at least for the time being. This is clearly an example of an establishment that has found to be unsafe, yet the risks posed by a relatively low level of compliance can be tolerated, at least until the business has had time to prove that it can correct the deficiencies found during inspection.

The Pankow pilot project did follow the perceived wisdom present in the BfR's risk profile, by making as much information available to the consumer, so that the decisions taken could be suitably defended:

We want to give the consumer as much information as possible. We felt it was important to show our inspection frequency and show the individual aspects of inspection, such as how a businesses' scoring went for its internal auditing or personal levels of hygiene... We even used to put photos up on our website to visually indicate this further but realised this was too time consuming. (Pankow_2013)

The German pilot studies became as much a measure of how compliant a business was, as they were about indicating and defending the actions taken by food safety inspectors.

Legal constraints to transparency

So, even though the representatives from the BfR and Pankow argued the importance of sharing as much information as possible to empower consumers, sharing any information has

proven to be an administrative maze. German local authorities are finding it difficult to even publish information (let alone barometers) that show concrete findings in relation to *koerperliche Unversehrtheit*. Under changes to the LFGB, made possible by the implementation of the Federal Consumer Information Law (*Verbraucherinformationsgesetz* – VIG), Länder authorities should publicly provide a list of such offences. The VIG, passed into federal law in 2008, allows for citizens to request government held health-related information or data. The law applies to products within the jurisdiction of the LFGB, as well as consumer products, as outlined in the Product Safety Act. The law should also enable authorities to actively communicate information to the public when there have been infringements of the regulations within the purview of the VIG. Specific to the LFGB, the Stuttgart Administrative Court further clarified the VIG by stating that a citizen's right to information is not dependent on a breach of the LFGB due to health grounds. In other words, the release of information should not be dependent on a clear health risk being identified. However, there has been plenty of criticism of the VIG, from both business interests concerned about the effect of such transparency, and consumer interest groups advocating a greater opening-up and ease of use in implementation. On a practical level, there have been concerns about the fees that are levied in order to process information requests (though these have since been reduced or abolished), as well as the time burden placed on completing requests due to administrative and legal hurdles that need to be overcome. However, it is the concern that such a law may impede the constitutional right of businesses to trade freely, which has had a fundamental bearing on the implementation of food hygiene barometers.

Debate over the extent to which business rights were being impinged, as well as the practical issues briefly discussed, ensured the VIG got off to a rough start. In 2012, the federal government, intending to inject some impetus, modified the LFGB so that authorities were obliged to publish lists of businesses that were responsible for serious violations of hygiene rules. Certain local authorities, with varying degrees of support from their Länder governments, saw this as a springboard to launch food hygiene barometers. As authorities began to publish serious violations on their websites, they were immediately subjected to legal challenge from businesses. The challenge hinged on three aspects:

- 1) What constitutes a serious violation?

- 2) What if violations don't have a direct impact on public health, and are instead related to the organisation of the company?
- 3) How will a business be able to cope with a black mark against its name, following its "naming and shaming" on a government site?

To date, German administrative courts have sided with any challenge to the publication of these lists. This has left blank lists on Länder websites, or no list at all. For example, the Niedersachsen page has cited the Higher Administrative Court of Lower Saxony's ruling that brought the constitutionality of the amendment to the LFGB into doubt. As there has yet been no review by the Federal Constitutional Court, the list is blank.

In 2015, the then Federal Agriculture Minister Christian Schmidt suggested a solution, hoping to circumvent the impasse. Schmidt argued the need for a hardship clause, which would give authorities the discretion to assess the impact of publicly naming a business and ensure that the business would not be unduly affected far beyond the outcome of the public being informed. Furthermore, any entry would have to be deleted the moment the business improves accordingly, and any record would have to be deleted after six months. However, there has been no subsequent movement and the Länder are still awaiting a clarification in the Federal Constitutional Court's legal position.

This precedent has clearly had, and continues to have, a knock-on effect for food hygiene barometers. This is because barometers go beyond simply identifying serious violations, and give an overall picture of the levels of hygiene within a business. The rulings in administrative courts have made it very difficult for local authorities to run barometers, as it has been relatively straightforward for businesses to challenge the barometer system. In November 2013 alone, the City of Duisburg had 8 lawsuits with regard to their *gastroampel* barometer, with one councillor lamenting:

The situation is currently unfair and unbalanced. It is too easy for businesses to sue and all they need to do is quote paragraph 40 [of the LFGB]. (Duisburg_2013)

A similar sense of frustration was clearly apparent within Pankow:

In September 2012, there was supposed to be a big change where German transparency laws were being revised with the creation of a new Consumer Information Law. However, there are still many loopholes and the Information Law is so vague. There has been no legal precedent set and because the law is so vague, there is a significant amount of successful legal action against local authorities.
(Pankow_2013)

Indeed, since then, Pankow's smiley system (and a similar scheme in neighbouring Lichtenberg) has been suspended. In March 2014, the Berlin Higher Administrative Court made such a ruling after two companies, who had been rated badly by these barometers, complained. The court ruled that only information on "identified breaches" should be released (in line with the 2012 amendment of the LFGB). Further, the court stated that these barometers were akin to reviews that would lead to consumers making a comparison of businesses, and that it is not for authorities to unduly influence a consumer's decision-making. Such a 'review' based system may also unduly negatively impact upon businesses. Finally, it is difficult for consumers to understand what underlies a barometer's simple integer score, whether it be to do with deficiencies in the products sold, or the organisational practice of the business, for example.

The *gastroampel* system in Duisburg, however, is still operational. Due to the high levels of uncertainty over the implementation of the VIG and amendments to the LFGB, the Duisburg government has decided to continue publishing its barometer until legal clarification is achieved. This was in reaction to a ruling in the Düsseldorf Administrative Court, where four catering businesses had objected to the City of Duisburg publishing inspection outcomes through its barometer (specifically through a mobile phone app that it had produced). The Administrative Court, which blocked the publication of the barometer, based its decision on three points:

- The VIG does not offer a legal basis for publicising data from individual businesses.
- The VIG does not provide for the publication of data in a traffic light format (i.e. red, yellow, green).
- The VIG only allows for the sharing of specific violations, or general findings from a food inspection.

The court recognised the importance of the ruling, and given the uncertainty over the VIG, recommended the ruling be assessed by a higher administrative court – such clarification, at time of writing, is still to be given. This in part reflects the highly complex nature regarding implementation of the VIG at Länder level, and the interplay between Länder administrative courts, the Federal Administrative Court and the Federal Constitutional Court. However, following the ruling in the Düsseldorf Administrative Court, the North Rhine Westphalia Consumer Board (which oversees barometers in Duisburg and Bielefeld), assuming there would be an appeal to a higher administrative court, stated:

Individual questions on official control of foodstuffs, as prescribed in the Consumer Information Act, involve far too many administrative hurdles that take too long. With our control barometer app, we offer fast and easy access to official results.

These administrative hurdles exist because both the VIG, and amended LFGB, do not provide clear indications of the *extent* to which public authorities can publish information about businesses, and how the needs of the consumer should be measured against the concerns of the business that is about to be exposed.

7.8.3 Political appetite for barometers

This legal indeterminacy has meant other local authorities have been discouraged from implementing pilot schemes of their own, fearing the time and costs that such exercises would involve. One civil servant in Duisburg argued that other local authorities have been complaining that a barometer would add further commitments to a food inspector's time. He claims this is an excuse and is simply a cover for local authorities not wishing to take on legal proceedings, perhaps a less altruistic motive in the eyes of the consumer:

Our barometer can be done on the spot during an inspection. It does not involve more food safety inspectors and the software is already there. It can easily be done; it is just a convenient excuse from other local authorities for why they do not wish to investigate such schemes. (Duisburg 2013)

A lack of political will in the face of Germany's poorly developed transparency laws has been felt within Pankow as well. Even though political support was gained when the scheme was first introduced, plans to extend the scheme from Pankow to the rest of Berlin led nowhere:

Berlin wanted to implement our system and came up with the Sicher Essen scheme. However, it didn't inform the public properly and had many legal problems. It needed the Berlin senate to step in and take charge as it was a Berlin-wide scheme, but they didn't want to be responsible for it, so the scheme fell away. (Pankow_2013)

This lack of central coordination is evident across other Länder. Bavaria, who voted against a national barometer scheme in 2011, argued that it wasn't because they weren't in favour of such public disclosure in principle, but because there was a whole raft of different schemes being proposed:

We had traffic light schemes, smiley schemes, stars and numbers being proposed without actually explaining how they explain to the consumer the risks involved. What does a happy face mean? What does a three out of five mean? (Duisburg_2013)

This comment helps explain how hard it is to achieve consistency across all the Länder - there were different local authorities proposing different schemes, with different interpretations.

However, according to a consultant who helped introduce the FHRS into the UK, the German pilot studies fell afoul of trying to report too much information to the consumers, leaving businesses to put forward the fairly simple case that these barometers weren't neutrally conveying scoring data, but were actively judging the businesses they scored:

The problem when you start throwing in photos, individual breakdowns etc. is that you are no longer passing on a score. You are actively saying to the consumer, "look at these photos and see how grubby this business is", you're actively drawing the consumer's attention to the worst aspects of the business. It's hardly a surprise that businesses are reacting. When they rolled out these schemes, at least at the beginning,

local authorities should have figured out that less is more; keeping it simple will ruffle fewer feathers. (Pankow_2013)

A lack of central guidance, according to this respondent, has cost these schemes any chance of success. This brings the discussion back to the delegation of responsibilities and competencies between the federal level and Länder. The BVL, with the competency to facilitate and guide cross-Länder discussion of best practice, is seen by many Länder civil servants as somewhat of a lame duck. For example, in Bavaria:

What does the BVL do? I really don't know to be honest. They come to our LAV meetings but just sit there. What more can be said about them? (Bavaria_2013b)

A similar view was expressed in Saxony:

The BVL has no real authority and no real power. Beyond organising meetings, its role in Länder dialogue is very limited. (Saxony_2013a)

However, as previously discussed, federal food safety institutions are actively trying to increase their responsibility. But the Länder do not wish to concede further competencies to them – a prime example being federal authorities taking over responsibility for inspecting food businesses that export out of Germany.

Germany is therefore left almost bereft of any of these food hygiene barometers. Even though it has had in many ways the same historical precedent to that of the UK, a combination of normative, legal and political issues has impacted on barometer rollouts. The normative description of German consumers in case law, casting doubts on whether consumers should be the final arbiters of judging a food business, has blunted one of the main tenants of these barometers – that consumer action would lead to behaviour modification of businesses and drive compliance up. The precautionary nature of German regulation has provided an inhospitable climate for risk integers that stray into the domain of uncertainty. The implementation of the VIG and amended LFGB have not clarified the situation, but instead served to create a legal quagmire from which there has been insufficient federal clarification. And finally, most likely because of all the preceding issues, the political will to push these

barometers on has weakened as most Länder take note of the uncertain and troubling times the few pilot projects have been through.

7.9 Conclusion

Comparison of food hygiene barometers within the UK and Germany reveal completely opposing experiences. Within the UK, due to the centralising food safety regime, coupled with a robust legal underpinning for transparency and a political zeal for the principles of nudge, food hygiene barometers have become established in the UK regulatory landscape. In Germany however, geopolitical fragmentation, competing constitutional rights and issues over interpretation of the empowered consumer have led to food hygiene barometers being struck from the German regulatory toolset.

7.9.1 An established UK system

It must be noted that in the UK, the development of food hygiene barometers has not been seamless. While the FHRS has been completely rolled out in England, Wales and Northern Ireland, it still presents several issues regarding approaches to risk. The first is that the FHRS could undermine the proportional inspection frequencies if EHOs are required to re-visit generally compliant businesses that are seeking full marks, at the expense of spending time with businesses that have achieved a low level of compliance.

Second, public pressure has caused certain local authorities to build their inspection frequencies around FHRS scores, which do not take into account the hazard section of a full inspection. This means that inspection frequencies would not take account of differences in the handling of higher or lower risk food or approaches, leaving frequencies based purely on levels of business compliance.

Finally, While the FHRS has now been implemented across all local authorities in England, Wales and Northern Ireland, variation in whether scores have to be displayed by food businesses across the three nations reflect some of the difficulties of implementing the scheme. Thus, while Wales has had mandatory display since 2013, and Northern Ireland since 2016, the display of scores is still optional in England, leaving English consumers to

consult a dedicated FSA webpage. One reason for this variation is that the British Hospitality Association has opposed mandatory display in England because it claims that there are discrepancies in the way that local authorities are awarding scores. Nonetheless, there is still some impetus for the introduction of mandatory display in England, not least because the media has made frequent use of FHRS scores to investigate restaurants. The basic premise of the FHRS, however – that it is both right and helpful to inform the public about the hygiene performance of food businesses – has gone relatively unchallenged.

7.9.2 An “unestablished” German system

In contrast, the German system of food hygiene barometers has been constantly challenged, and the empirical evidence gathered points to three main reasons for this. The first problem has been German federalism, which has prevented national implementation of food hygiene barometers in the absence of agreement amongst the 16 German states. Despite efforts in 2011 to have a requirement for barometers written into federal law, the then federal minister for Agriculture, Nutrition and Consumer Protection, Ilse Aigner, conceded defeat after Bavaria objected. This veto left individual states to consider whether they wanted to introduce their own pilot schemes.

A second, and perhaps more significant problem, however, has proved to be the German constitution. Despite new laws aimed at improving consumer access to food safety information, constitutional challenges to the legality of the few pilot schemes that have been introduced have forced them to be abandoned. Thus the 2008 Federal Consumer Information Law (*Verbraucherinformationsgesetz – VIG*) and changes to Germany’s underlying Food, Feed and Consumer Goods Code (*Lebensmittel, Bedarfsgegenstände und Futtermittelgesetzbuch – LFGB*) required local authorities to disclose serious violations of hygiene regulations by food businesses. The problem, however, has been that consumer rights to information have to balance two important pillars of the German constitution; i.e. the rights of businesses to trade freely against the rights of the public to protection against bodily harm (*koerperliche Unversehrtheit*). Proposals to introduce a food hygiene barometer system consequently prompted a debate between politicians, caterers and public interest groups as well as legal challenges over whether barometers disclosed violations of sufficient severity for rights to protection against bodily harm to trump rights of businesses to trade freely. To date, all administrative courts have found in favour of businesses that have filed against

locally run barometers on the basis that the VIG does not offer sufficient legal basis for publicising data from individual businesses.

A third problem has been a conflict between the basic conceit of leveraging the agency of empowered consumers to shape business behaviour that lies at the heart of hygiene barometers and a German legal view of consumer sovereignty. Consumer sovereignty – the idea that consumers are the best judge of what products benefit them the most- is an unexceptional idea in the UK insofar as regulation is seen as correcting market failures that obstruct effective consumer choice. German legal commentators have argued, however, that the German courts view a consumer as someone who is incapable of taking informed decisions, and who requires the paternalistic oversight of the state. In that German context, the basic conceit underlying food hygiene barometers will struggle to make sense.

7.9.3 Implications

Currently, both Germany and the UK have food safety regimes that are almost entirely harmonised under the same EU food law. One might therefore assume that the implementation of food hygiene barometers would follow broadly a similar course and, indeed, in Germany, that there might be stronger reasons to expect them than the UK. However, that assumption has not proved to be the case.

The case of food hygiene barometers shows how issues of consumer sovereignty and its empowerment through the application of new forms of regulation, such as nudge, can be shaped by a country's constitutional context. Whereas the legal and political context of the UK provided fertile ground for the introduction of barometers- albeit with minor variation-, the conceit of liberal paternalism that underlies them failed in Germany because of federalism, constitutional protections for businesses to trade freely and a paternalistic legal construct of the consumer. The lesson for the transferability of other new regulatory ideas across Europe is that we need to think more carefully about how such ideas interact with some very basic conceits of how different states govern harms to their citizens.

Chapter 8: Discussion and Conclusion

8.1 Introduction

As the previous empirical chapters have indicated, despite the enthusiasm of both UK and German national administrations to implement risk-based approaches to enforcement as the EU intends, the outcome of such implementation can be substantively different. This is not simply down to differing interpretations of EU regulation by Member States, but also because of a myriad of reasons such as historical practices, institutional arrangements and constitutional barriers. Chapter 4 served to provide the historical context for food safety regimes in the EU, UK and Germany. This chapter indicated that historical practices continue to shape regulatory practices differently in both the UK and Germany, despite the emergence of a highly harmonised EU food safety regime at the turn of the 21st century.

The drivers and constraints to the application of risk-based approaches occur along the regulatory pathway from supranational standard setting, to national interpretation and dissemination of rules, through to local enforcement of those rules. This chapter will further tease out the main findings from the three case studies assessed, and explore how these findings may relate to future food safety regulation, as well as the broader academic literature on risk. The next section will provide a summary of the key points that emerged from the empirical chapters.

8.2 Summary of findings

8.2.1 Chapter 5

Chapter 5 showed that even though the European commission has been eager to apply risk-based approaches in policy-making, in particular food safety, there are numerous roadblocks to such an aspiration. Of issue here is the wording of the GFL, which states that no unsafe food shall be placed on the European market. This makes the standard of the EU food safety regime very simple to understand – the standard is safety. The expectation here is that if any food is found to be injurious to human health, or is not fit for consumption, then that food should not be sold. There is no sliding scale of proportionality that is indicative of a risk-based approach; instead there appears to be the dichotomy of choice that benefits a hazard-based approach to regulation. Either food is found to be unsafe and is banned, or it is not and

is permitted. Discussion with respondents working within EU institutions revealed that there is an underlying assumption amongst consumers that the food they buy in the supermarket shelves is safe. And even though the public debate in recent years appears to have moved away from issues of safety to issues of food security, this was seen by EU regulators as an endorsement of the high level of food safety that has been achieved. This high level has to be maintained, with regulators showing commitment to regulate harms, before the likelihood of those harms occurring has been calculated. This commitment lends itself to focusing on hazards, rather than relying on business compliance of regulatory standards, which would indicate the likelihood of those harms occurring and be risk-based in nature.

At an EU level, however, the definition of risk is contested. Even if interpretation of the GFL is not intended to be taken quite so literally, and the goal of safety is to be achieved through risk-based approaches, discussions with respondents revealed difficulties over how to set acceptable levels of risk across 28 Member States. This is an understandable state of affairs that is symptomatic of a federal structure, where all states must come to an agreement. However, further research revealed that at an EU level there is not just discussion about setting an acceptable level of risk, there is a more fundamental debate over the different types of risk that should inform regulation. As risk appears to be rarely defined within these discussions, different actors involved in the standard-setting could be talking about different risks surrounding the same problem, whether that be societal risks, institutional risks or economic risks.

The EU food import regime offered a very interesting insight into how the EU determines risk. The terminology of risk is deeply embedded within this regime, as entire categories of food are labelled “high-risk” – requiring 100% physical checks (as well as documentary and identity checks), unless these checks are reduced as outlined under directive 94/360/EC. However, there was uncertainty over how the various levels of checks in 94/360/EC were determined, and why they have not been updated since the directive was introduced in 1994. Despite the founding of EFSA in the intervening period, which could provide risk assessments to underpin the levels set, there has been no fundamental change. Further research indicated that labelling of all POAO as high-risk is systematic of path dependency resulting from historical practices which were almost exclusively focused on the safety of meat supplies, and were underpinned by the professional interests of the veterinary profession. In the past decade, the risks posed by FNAO have become more salient, leading

to the high-risk checklist in regulation 669/2009, which determines percentage identity and physical checks for certain FNAO. This development would indicate that the regime for FNAO is being brought into line with the one for POAO – and that the food import regime overall is heavily reliant upon the determination of high-risk products. However, the term “high-risk”, especially in the case of POAO, does not appear to be supported by scientific determination of the risk posed, and once again lends itself more to a hazard classification in stating all POAO to be high-risk. While there have been important technological advances, such as the TRACES risk management system for POAO, which identifies higher risk imports through constantly updated trade data and RASFF notifications, it does not override the checks as laid out in 94/360/EC. It would therefore appear that the terminology of risk is becoming conflated with that of hazard, as the food import regime seeks to reassure consumers by referring to the control of high-risk products, without necessarily providing the underlying evidence to qualify the determination of high-risk.

The food import regime also showed that enforcement approaches that have become synonymous with risk-based approaches are not apparent in this case. It can be argued that food import inspection regimes are based upon command and control approaches to ensure specific rules are followed, as opposed to soft compliance approaches characterised by a broader focus on the compliance of businesses, and systems of self-regulation, as a proxy to regulating risks. Should an importer not follow the rules as set by the food import regime, their consignments will be either rejected or destroyed. Furthermore, co-regulatory dynamics that are apparent in other parts of the EU’s food safety regime (such as earned recognition for inspections of food businesses) are not at all apparent at food import.

8.2.2 Chapter 6

Chapter 6 compared national and local practices relating to food safety enforcement of food businesses within the UK and Germany. The research found that even though there is appetite for risk-based enforcement approaches in both countries, institutional organisation, fragmentation and historical enforcement practices reveal significant contrasts in enforcement cultures, leading to ramifications for the application of risk-based approaches.

In the UK, there is a high degree of centralisation, with local authority enforcement directed by the Food Law Code of Practice, a detailed document that outlines the risk scoring of food businesses to determine inspection frequencies. The FSA also plays a central role as it provides oversight principally through the audit of local authorities. In Germany, the situation is quite different. As the Länder have individual competency for the enforcement of food safety regulation, the federal level is relegated to a largely coordinating role, facilitating contact between the 16 Länder. The AVV-Rüb provides general administrative principles for the control of food and feed, but isn't as detailed as the UK's Food Law Code of Practice, owing to greater level of fragmentation within German food safety enforcement. While the BVL and Länder working groups such as the LAV have increased harmonisation through the sharing of best practice, implementing new regulatory approaches across Germany remains difficult. This has consequences for the implementation of national-level risk-based approaches, unlike in the UK where national schemes are far more easily implemented. Examples in the UK include the introduction of the Primary Authority Scheme, which claims better risk-based targeting of regulatory resources, and the FHRS, which communicates the level of compliance to food hygiene standards as a proxy measure of foodborne illness risk (this case study is discussed in detail in Chapter 7). In Germany, informational asymmetries between the federal level and local authorities provide an immediate obstacle to implementing national schemes.

Despite the establishment of enforcement practices that were viewed as more risk-based in the UK, important issues were highlighted in their implementation. In particular, the role in measuring confidence in management of food businesses, with questions asked over the extent to which confidence in management was a suitable proxy measure of food hygiene risks within the business. This revealed a tension where some local authority inspectors are much more comfortable focusing on the actual hazards in food businesses, rather than trying to determine the likelihood of harm through assessing internal systems of business checks and balances, as signified in the confidence in management part of an EHO inspection. This concern spilled over into discussions on HACCP, as HACCP is the primary system for businesses to implement their own checks and balances. Concerns over business self-audit were raised less by enforcement officers in Germany. The reason for this is most likely due to the core responsibilities enforcement officers argued were a part of their jobs. In the UK, while risk-ranking establishments for inspection, and the subsequent inspection were seen as key parts of the job, providing education and support to food businesses was viewed as

equally important. A majority of food businesses within the UK do not need any preauthorisation or qualifications, leaving a multitude of SMEs that simply lack the expertise to understand or comply with food hygiene legislation, never mind understand the risks that such legislation seeks to mitigate. In Germany, whilst the same pressures exist for SMEs, all food businesses are required to be a member of an industry association – specifically the IHK. German inspectors therefore place more reliance on the supporting role of these associations, and while this does not mean that German inspectors don't provide education to food businesses, it is not seen as such a core function of the inspector's responsibility, in contrast to their UK counterparts.

Concerns over measuring business compliance were brought out further in discussion of the UK's implementation of the Primary Authority scheme. As the primary authority selected to partner with a business takes charge of assessing confidence in management across that business, it absolves EHOs of assessing confidence in management in any branches of the business in their local authority. Risk-based selection is one of the primary drivers behind the Primary Authority scheme, as leaving a single authority to oversee and certify a single business' audit and management systems, diminishes the need for EHOs to inspect those aspects across branches of the business, allowing enforcement resources to be focused elsewhere. However, concern was raised over whether this risk-based approach did indeed help target resources to the greater risks, if companies with multiple entities were effectively being homogenised into one operational unit. Essentially risks were being assessed based upon a central plan, and the assumption that there is consistent application of that plan throughout all branches.

Co-regulatory dynamics are present both within the UK and Germany, with 'earned recognition' examples in both countries indicating that business systems of auditing compliance are being taken into account when inspection frequencies are calculated by government inspectors. Examples include the Red Tractor scheme in the UK, and the QS scheme in Germany. The increase in co-regulation is important for two reasons: first, that competent authorities are taking a more literal approach to the GFL's stance – business is responsible for the safety of food on the market and so business should be responsible for more checks and balances; second, that authorities would argue this is risk-based, in that restricted regulatory resources can be designated to food businesses that aren't certified compliant under these business schemes. However, these schemes have greater significance

for Germany, in that they offer a means of circumventing constraints on harmonisation caused by fragmentation. This further emphasises the role of professional interest groups in Germany, as they not only have a central role in reaching standard-setting consensus with government institutions, but they can also overcome the fragmentations that divide state institutions.

Comparison of the two countries' local enforcement systems reveals quite differing approaches to the acceptability of risk and the enforcement arrangements supporting the regulation of risk. While Chapter 4 showed that the evolution of food safety regulation in the UK and in Germany was broadly similar, professional groups underpinning enforcement show significant difference. Within the UK there has been a generalist approach to food hygiene inspection, with inspectors of public nuisances and then environmental health officers represented by what is now the Chartered Institute for Environmental Health, and falling under the auspices of a government department (currently the FSA). In Germany, however, responsibility for inspection and sampling of food businesses at first relied on public self-help associations and the police, but became increasingly characterised by the veterinary profession and a new profession of food chemists. This has historically led to differing composition of inspection personnel across the Länder, with varying enforcement practices. The autonomy of the Länder is underlined by differing expectations of food safety regulation. Current expectations can be based upon historical practices, such as in the case of the former GDR's blanket approach to food safety enforcement, having many food safety inspectors to mitigate any politically damaging food safety incident. This has led to discomfort from inspectors in the East German Länder having a rolled back inspection regime, reliant on risk-based targeting, as this differs from the "catchall" approach of the GDR. There also appear to be fundamental differences in expectation in the regulation of specific food products, such as in the example cited – the regulation of nicotine in eggs in Saxony and Bavaria. This case is an example of the power of private industry groups to set the level of risk appetite (as the risk appetite was set much higher in Saxony, where there is a large egg industry). While there are differences of expectation across the UK, and in countries where responsibility for food safety regulation has been devolved, it is not on the same fundamental level as in Germany, as legal subsidiarity (as indicated in Germany by the presence of administrative courts in different Länder) does not exist between different local authorities or regions of the UK. While the presence of different risk regulation regimes within Germany is not a problem in and of itself, it is difficult to see how such regime

proliferation fits into an increasingly harmonised system of EU food safety. And with differences in practice between, and even within Länder, how EU audits of two or three Länder at a time, will give an overall picture of the German food safety system.

The role that national competent authorities play in the enforcement of food safety regulation shows a further important contrast between the UK and Germany.

The difference reveals at what level, national or regional/local, risk appetite is set. In the UK, the FSA sets the risk appetite, through the guidance it provides to local authorities. This was shown for example, in response to the *E. coli* incident in 2007. Conversely, in Germany, the Länder have far more autonomy when it comes to setting acceptable levels of risk, unless there is a federal administrative law that regulates a specific product or approach. The German *E. coli* incident of 2011 initially showed Länder authorities responding to the crisis through their own channels, rather than relying on any central federal channel of risk communication or crisis management. The outcome of that *E. coli* crisis was that it served as one of the few occasions where the German federal level could claw back some responsibilities from the Länder level, with the recommendation that central crisis management should be strengthened with the creation of a crisis task force within the BVL. Indeed, other examples of the federal level trying to gain more competency from the Länder have failed. The relative power of the Länder, and crises such as the *E. coli* incident, does show that accountability is shared between the federal level and Länder. In the UK on the other hand, discussion with local authorities about the impact of major crises (such as the BSE crisis) shows that accountability lies very much with national authorities. This would suggest a much more hierarchical food safety regime in the UK, as opposed to a relatively organisationally flat food safety regime in Germany. This provides further evidence as to why it may be easier for the EU to implement harmonised risk-based approaches in the UK, as opposed to in Germany.

8.2.3 Chapter 7

Chapter 7 provided an important insight into national and local approaches to risk in food safety, as it focused on an area where the EU does not have direct oversight, namely the implementation of food hygiene barometers. This chapter also revealed the greatest contrast in food safety regulation between the two countries, with the UK having fully implemented

(bar Scotland) a barometer system in the shape of the FHRS, whilst in Germany there is barely a single local pilot project still running. The findings from the two countries leave two narratives: how the FHRS can be the victim of its own success in the UK; and Germany's difficulty in managing and communicating uncertainty in the regulation of risk.

With the UK, in principle the FHRS indicates the successful implementation of a system that leans heavily on the principles of nudge to ensure that informed consumers make a choice of food business based on communication of risk integer scores. This system has an added benefit in that consumer choices inform businesses to improve their hygiene, ensuring they keep their customers. A business that scores a low FHRS can expect that informed consumers will look elsewhere. Although the research on the efficacy of food hygiene barometers is still contested in terms of measuring the ultimate indicator of success – a reduction in foodborne illness because of these barometers – the implementation of the FHRS across all local authorities in England, Wales and Northern Ireland shows comprehensive implementation of the scheme by the FSA and local authorities. However, the lack of mandatory display of FHRS scores in England and Northern Ireland, shows the role played by private interest groups, in this case lobbying done by food business associations.

However, very little research has been conducted on the effect that the FHRS has, and may have, on the enforcement practices of EHOs. Discussion with respondents revealed three important constraints. The first is centred on the appreciation that the FHRS is not a complete reflection of an EHOs inspection, as outlined in the Food Law Code of Practice. The FHRS scoring is only based upon business compliance with food hygiene standards. The hazard part of an inspection, such as assessment of the types of products that the business is handling, or the vulnerability of the consumer, is not included in the FHRS scoring. Pressures placed upon EHOs have caused some local authorities to pay more heed to the FHRS in setting their inspection frequency, rather than the full inspection that includes the hazard. This means that the FHRS has evolved from a risk communication tool to a risk management tool, without sufficient regard for the very hazards that food safety regulation should seek to cover. A hypothetical example to illustrate this point could be that of two food businesses, inspected on the same frequency due to both scoring 5 out of 5 on the FHRS. However, if one business was dealing with high-risk products, say raw meat, whilst the other was handling low risk products, say tinned baked beans, the first business could have greater potential for causing harm and this would not be picked out in a measure of compliance alone.

The second issue concerns unintended consequences, due to the statutory right of businesses to request a revisit within three months from an EHO, following an FHRS award. The concern here is that businesses that are at least generally compliant with food hygiene standards, and score 3 or 4, request revisits to attain a 5 status as soon as possible. This would draw EHO resource away from the less compliant businesses that score 0, 1 and 2, undermining a proportional risk-based approach to enforcement. While there is currently little evidence to support this hypothesis, EHOs are concerned that if the popularity of the FHRS continues to rise, this will incentivise near full compliant businesses to achieve full marks from the FHRS, requiring more EHO resource.

Finally, the FHRS has put enforcement activities into the public limelight. This should help drive up harmonisation within and across local authorities, as EHOs will be keen not to look out of sync with the general level of scoring across food businesses. However, the public display of scores prevents EHOs from tweaking their scores in order to alter inspection frequency to better match the inspector's subjective interpretation of a businesses' level of hygiene. While this has the benefit of preventing inspectors from 'fiddling the system', it means that a degree of subjectivity is lost in the pursuit of objectivity.

The largely failed experience in Germany regarding food hygiene barometers has reinforced the view that it is difficult to communicate uncertainty in Germany. Considering that one cannot have risk without uncertainty, this has profound implications for the application of risk-based approaches.

The weakness of the country's consumer information law was central to food hygiene barometers failing in Germany. Despite the law allowing consumers to ask local authorities about findings from food business inspections, which would provide the backbone to a transparency system like food hygiene barometers, food businesses were quick to challenge such a system in the administrative courts. This resulted in administrative rulings which stated that authorities could only publish concrete findings. Within Germany's heavily juridified system, trying to prove that a finding is suitably concrete has proven very difficult, and has led many authorities to abandon the publication of any lists outlining failings found in the inspection of food businesses. This in turn has led to more intricate food hygiene

barometer pilot projects either being abandoned or awaiting further clarification from higher administrative courts.

This state of affairs reveals competing constitutional provisions within German basic law. While on the one hand, the German constitution guarantees the protection of all German citizens, it also guarantees the freedom to trade. While the publication of food hygiene compliance lists and barometers would be seen as a move to protecting consumer health, business would argue that such publication would put a black mark against listed companies – even if it turns out that such a mark was given in error, or the business subsequently improves. The outcome of the administrative court cases outlined in Chapter 7 is that business interests appear to have trumped interests for public protection. Furthermore, the simplistic legal depiction of a consumer within German law (the German courts present the consumer as someone who cannot take care of himself, and requires support from the state) appears to be someone who cannot make the required informed decisions that would make a barometer system useful.

Couple constitutional roadblocks with Germany's incredibly tight data protection laws and the lack of an agreed barometer system for use across Germany, and the infeasibility of food hygiene barometers in Germany is only increased. However, what the experience of food hygiene barometers in Germany shows, is the difficulty with communicating uncertainty. The German administrative courts operate in a dichotomy of safe/unsafe, and any pronouncement that falls in between those fixed poles will find itself under pressure from competing constitutional arrangements. Risk-based systems that report uncertainty in relation to business activities will soon find themselves in hot water.

8.3 Adequacy of the research

When reflecting on the research contained in this thesis, some comments need to be made about the limits of the methodology employed. First, in order to draw conclusions on the food safety regime in the UK, Germany and the EU, only three sub-regimes were selected for research. Though I have argued that these were the critical case studies to provide significant comparative insights along the regulatory pathway of the EU food safety regime, other food sub-regimes could have been investigated that might have yielded different findings. That can

only be tested by further research. Second, in selecting enforcement officials to interview within Germany and the UK, a comparatively small selection of Länder authorities and local authorities were unavoidably chosen for reasons of feasibility as well as practicability. Although selection of these authorities was based upon important criteria, as set out in Chapter 3, respondents from other authorities might have been able to provide further contributions to the research. Third, as German is not the native language of the researcher, due consideration needs to be given to the inevitable interpretative problems of using translations of German texts for documentary analysis; a significant issue which had to be carefully handled when it came to understanding subtle linguistic differences over the use of risk terminology. Finally, a more surprising finding was the paucity of English or even German texts on the evolution of food safety enforcement practices across Germany, which consequently demanded considerable unanticipated efforts to anchor the analysis within the historical contexts of the food safety regimes of the UK and Germany.

8.4 Linking the research to the literature on comparative approaches to risk-based regulation

The outcomes of research from this thesis contribute to the comparative literature that looks at the roll-out of risk-based regulatory instruments as universal tools of regulatory reform. There is a growing corpus of research that seeks to document risk-based regulation as a harmonising mode of regulation across national boundaries. However, much of this effort has either been undertaken at a rather macro-level, such as Vogel's comparison of North America and the EU (Vogel 2012); or has principally focused on Anglo-Saxon countries (e.g. Black 2010). This research, however, adds to more fine grained analysis in European settings, such as that of Krieger (2012) and Rothstein, Borraz and Huber (2013), by providing an in-depth comparison of how risk concepts and tools have shaped, or are shaping, regulatory practices and cultures in the UK's Anglo-Saxon liberal policymaking traditions, and Germany's federal corporatist traditions.

In so doing, this research has examined the political contexts of risk-based regulation, such as the tension between the technocratic discourse of acceptable risk and public demands for safety; a tension that is inherent to the dilemmas of how to deliver the promise of safe food in a risk-based way. Likewise, the research has pointed to the way in which risk ideas and

practices have been shaped by private, public and professional interest group dynamics; one notable example being the role of the veterinary profession in ensuring that all POAO remain designated as “high-risk”.

This research, however, has also pointed to the way in which the implementation of risk ideas and tools have been shaped by more hardwired national contexts that allow for parallels to be drawn with studies of risk-based approaches in other domains. For example, the research has identified geopolitical fragmentation as an important variable in understanding the extent to which risk regulation regimes are consistent within just one nation state, as both Lodge (2001) and Krieger (2012) found in how Germany dealt with dangerous dogs and flooding respectively. The research has also pointed to the importance of constitutional contexts to explain variation between Germany and UK. Likewise, it has pointed to the importance of governance traditions in shaping the implementation of risk ideas, most notably in the way that Germany’s proclivity for formal corporatist, sectoral governance – such as trade associations taking on responsibilities to educate their members on food hygiene standards – has had very different consequences to the UK’s tradition of government inspection combined with voluntary sectoral activity; contrasts which may well be found in other risk domains.

8.5 Discussion across the case studies

The research conducted for this thesis revealed a high number of factors that contribute to the application of risk-based approaches across the UK, Germany and the UK. The three case studies selected ensured that research was undertaken at supranational, national and local level, to ascertain where in the food safety regime the constraints and drivers to risk-based regulation are found. Reflection on the outcomes of the findings across the case studies revealed three main findings that speak more generally to the efficacy of implementing risk-based approaches, which are summarised below.

8.5.1 Regulating hazard or regulating risk?

While there was enthusiastic discussion about risk-based approaches across the three food safety regimes of the EU, Germany and the UK, the three case studies revealed a

predisposition towards regulating hazard, rather than risk. This predisposition in many ways reflected the wording of the GFL, whose hazard-based assertion that no unsafe food shall be placed on the market, was not immediately recognisable as accommodating risk. At food import level, the determination of all POAO as high-risk, and requiring either a 100% inspection regime, or a reduced inspection regime that does not appear to be underpinned by the tools of risk analysis, does not suggest a robust risk-based approach.

At a local enforcement level within the UK, EHOs interviewed were uneasy about focusing all inspection on measuring internal business checks and balances. Discussions on the role of confidence in management in the inspection of a business, and the role of HACCP revealed that EHOs preferred to focus on the hazards themselves, rather than lose sight of them by focusing on the degree of business compliance with regulatory standards. Their unease is significant because the FHRS is purely concerned with the risk of compliance, to the extent that the hazard part of an inspection is disregarded. This is acceptable for when the FHRS is used as a risk communication device, but when regulatory resources are directed based upon the FHRS, there is real danger that the actual harms posed to consumers, with which a food safety regime should concern itself with, are missed.

8.5.2 The applicability of risk-based approaches

Despite the eagerness within both the UK and Germany to implement risk-based controls, the experience in the two countries has been very different. While the UK has relatively easily implemented risk-based approaches (through Primary Authority and FHRS), the experience in Germany highlights important constraints. These constraints refer to the fundamental implementation of risk-based approaches, as well as the implementation of a highly harmonised EU-wide risk-based approach within food safety.

Constitutional considerations in Germany and their ensuing legal principles can easily undermine risk-based approaches. Unsurprisingly, the principle of precaution (*vorsorge*), which is entrenched in German regulatory decision-making, leads to a greater reliance on regulating hazard, rather than risk. Perhaps more surprisingly, constitutional requirements can clash with one another. This is apparent in the failed attempt at food hygiene barometers in Germany, where weak consumer information laws have been trumped by businesses'

freedom to trade. As a result, only “concrete findings” can be communicated, and so uncertainty becomes highly problematic and deeply juridified. It also means that the responsibility falls on regulators to prove that a product or process is unsafe, or their findings cannot be published. This contrasts with regulators at a federal level, who claim that due to precautionary approaches, new products or processes must be found to be safe, before being allowed onto the German market. Either way, legal recourse in Germany requires a high degree of certainty in determining the safety or “unsafety” of a product. Determination of risk to account for levels of uncertainty appears to be less welcome in Germany, than the UK.

Finally, the ideal of a harmonised risk-based EU food safety regime is difficult to picture when applied to a federalised country like Germany. The geopolitical fragmentation indicated by autonomous Länder, with embedded historical practices and norms, and differing approaches to risk makes it difficult to assimilate these risk regimes under one central regime.

8.5.3 The vagueness of risk

Discussion with respondents across the EU, Germany and UK revealed a fundamental question – exactly what risk are we talking about in the food safety regime? Although risk is understood in a regulatory setting to exclusively mean the prioritisation of constrained resources, the risks targeted are usually ill-defined, whether they be societal, institutional, or economic. The terminology of risk is even invoked when it is hard to ascertain where risk features in the ensuing regulation. For example, risk has clearly become a guiding rationale in the EU food safety regime, but sometimes this does not correlate to a risk-informed approach. Path dependency behind the designation of “high-risk” POAO shows that the terminology of risk is used to rationalise regulatory action that isn’t risk-based itself. This emphasises the salience of risk in modern regulation, when its terminology is even used for effect.

On a local level, as previously mentioned, the application of risk-based approaches within the UK food safety regime increasingly focus on the risk of non-compliance, rather than on the harm itself. Beyond this, risk-based approaches can undermine the proportional system of enforcement they seek to promote; one example here is food businesses that have scored 3 or 4 in the FHRS, requesting a re-visit to attain a 5. This takes EHO resource away from establishments that have the greater risk of non-compliance, namely those with 0, 1 or 2.

These examples are indicative of how the plurality of risk terminology can lead to unintended consequences, as regulators chase after a type of risk that is not linked to the reduction of societal harms.

8.5.4 Wider implications of this research for risk-based regulation

While this thesis has focused on food safety, the research highlights important variables that underpin the efficacy of risk-based approaches that are not constrained to this single policy domain, or indeed its geographical remit.

Fundamentally, this thesis supports the warning given by Lupton (1999) that while the language of risk is becoming increasingly pervasive, there is an important need to identify and assess how the application of risk ideas play out in different contexts and across different populations. For even though this thesis has shown an enthusiasm at the EU level to anchor food safety regulation within risk governance, over 15 years after this was explicitly laid out in the General Food Law, there continues to be great debate over the language of risk. Specifically, there appears to be uncertainty over what risk is being regulated against, how risk analysis is constructed (as in the grey areas between risk assessment and risk management), and how the acceptability of risk is determined across 28 diverse Member States. It would therefore be interesting to see whether other supranational organisations, such as the OECD or World Bank, suffer from these same issues concerning the diffusion of risk ideas. The evidence gathered in this thesis would suggest that such issues would be prevalent across all supranational standard-setting bodies.

This thesis has also indicated that there are legal and constitutional barriers to the extent to which risk-based approaches can be considered as universal. While the evidence gathered with relation to the UK indicates that risk-based approaches have increased harmonisation across local authorities, such as with Primary Authority, in Germany this is not the case. The juridified nature of enforcement cultures within the fragmented polity of Germany means that law courts, both administrative and constitutional, are the arbiters for increasing harmonisation. Germany is therefore affected by legal norms, some that manifest in a way that is restrictive to the roll-out of risk-based regulatory toolsets. A key constitutional issue concerns the grounds for regulatory interventions, specifically what thresholds have to be met

in order to justify an intervention. Friction between constructional precedents, such as the right of businesses to trade freely against the public right of protection against bodily harm shown in the case of food hygiene barometers, have a profound impact on where the bar for regulatory intervention is set. Other legal hurdles to risk-based approaches include Germany's long-standing commitment to the precautionary principle and the reluctance of German courts to define consumers as sufficiently informed to be able to make decisions as required within the context of 'nudge' approaches. The majority of legal constraints highlighted within the Germany are to do with constitutional interpretation, an exercise that does not explicitly take place within the UK case. This author would therefore suggest that the application of risk-based approaches may prove problematic not simply within a fragmented federal polity, but also within a polity with established constitutional arrangements.

A third general observation that can be taken from this thesis is the role and power of professions. Within food safety, the German corporatist approach is clearly evident, with professions tasked with enforcement, such as food chemists and vets, holding influence along with Lander and national government, as well as industry and consumer protection NGOs. In the UK, this proliferation of important professional interests is not as apparent. Evidence provided in this thesis suggests that in the UK, Environmental Health Officers were less able to 'resist' changes in regulatory approaches. In Germany, food safety inspectors appeared better linked into the standard setting machinery, whether this was through established approaches to corporatism or the high level of local autonomy afforded within the policy domain. Such differences would support Katzenstein's (1987) assertion that within Germany, power relations are carefully balanced through the need for cooperative arrangements, as opposed to a greater centralisation of power within the UK polity. The conclusion to draw here is that, with other new regulatory approaches, risk-based approaches may face more hurdles to overcome before they are properly implemented in a consensus-seeking Germany rather than the hierarchical context of the UK.

The two countries provide differing patterns with regard to the universality of risk-based approaches. Within the UK, risk-based approaches are actively used as a means of increasing harmonisation across local authority enforcement, whether that be through the Primary Authority Scheme or through FHRS. It could therefore be argued that risk reduces diversity of regulatory enforcement practices here. In Germany, and despite requirements in AVV Rüb for inspections to be risk-based, there is no indication that such approaches have had a

substantive harmonising effect on German enforcement practices. With significant variation shown between Länder in (politically) setting acceptable levels of risk, differing historical cultures of enforcement, and variance in the institutional makeup of enforcement services and professions, this makes the effective implementation of any harmonising federal regulatory tool difficult if not impossible. This would suggest that, with any policy domain, there needs to be a sufficient political and legal context for risk-based approaches to thrive. A geopolitically fragmented country that has organisationally flat institutional arrangements for regulation and strong corporatist traditions and constitutional norms, such as Germany, has provided greater hurdles to risk-based approaches than the centralised and organisationally hierarchical UK.

8.6 Conclusion

This thesis has been chiefly concerned with the study of risk-based approaches to the regulation of food safety within the UK and Germany. Two wealthy, industrialised countries, which in relation to food safety are harmonised under the same EU regulations, both publicly welcoming the increased regulatory efficiencies that risk-based approaches offer – surely risk will be implemented in the same way? Through the selection of the three case studies for this thesis, the simple answer is “no”. However, the differences that the three case studies tease out are of relevance not only to the policy domain of food safety, but also to broader research on risk-based regulation.

At the forefront of EU food safety regulation, there is a tension between hazard and risk. While the regulation on official controls, 882/2004, requires the enforcement of food safety to be risk-based, the underlying GFL, as outlined in 178/2002, stipulates that no unsafe food shall be placed on the market. At once, we have an ontological debate about what an acceptable level of risk is, and how it correlates to a standard of safety. Risk is seen as an organising rationale within regulatory discourse, but its terminology can be employed without the tools of risk analysis being brought to bear – as evidenced by the use of “high-risk” to refer to all POAO within the EU food import regime. Indeed, the clamour for implementing risk-based approaches must first be tempered by a fundamental question – what risk are we trying to regulate? In food safety, is this the health risk to consumers? The institutional risk to business? Or regulators? The economic risk to trade?

Having a tempered approach to introducing risk-based approaches applies to national settings, as well as supranational ones. The experience of Germany across the case studies within this thesis, has shown that through a mixture of geopolitical fragmentation, competing constitutional arrangements, and historical practices, risk-based approaches can either falter (such as with food hygiene barometers), or splinter into a myriad of different risk regimes that reflect the fragmentation of a federal state. This fragmentation poses questions for the highly harmonised nature of the EU food safety regime, and how the EU can suitably capture the multiplicity of risk regime within one country.

The experience of the UK across the case studies selected shows a more hospitable political and legal environment for the application of risk-based approaches. However, this does not mean that the application of these approaches did not reveal some searching questions about the role of risk in regulation. For example, the FHRS, though ostensibly a tool of risk communication, has become a risk management tool as EHOs look to regulate their frequency of inspections on the FHRS's publicly available scores. This would preclude the EHO's full inspection of a business, which also includes assessment of hazards. This is omitted from the scoring matrix of the FHRS, which is exclusively concerned with business compliance of regulation. A constant question underpinning discussion with UK regulators was whether the calculation of the risk of non-compliance acts as a suitable proxy of assessment for the risk of foodborne illness?

This brings the issue full-circle round to what is the risk we wish to regulate? Part of the reason as to why this question is posed, is due to the ill-defined terminology of risk. It is now more than 37 years since the watershed US Supreme Court rulings on OSHA's regulation of benzene, that put risk-based regulation firmly on the regulatory map. However, there is still a great deal of indeterminacy regarding the types of risk that a regulator should regulate. So, this is an appeal for greater collaboration between the academic world of risk, and the regulatory world of risk, to clearly define the different types of risk, and how they fit into regulatory dynamics and societal contexts. In the meantime, the fallacy that a risk-based approach can act as the unifying principle across and within nation states will continue to falter, as I hope this thesis has shown.

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Appendix 1: List of Interviews

#	Reference	Organisation
Germany		
1	Hamburg_2013a	Hamburg Government
2	Hamburg_2013b	Hamburg Government
3	BW_2013	Baden-Württemberg Government
4	Munich Airport_2014	Munich Airport
5	Bavaria_2013a	Bavaria Government
6	Bavaria_2013b	Bavaria Government
7	Pankow_2013	Pankow Government
8	BVL_2013	Federal Office of Consumer Protection and Food Safety
9	BFR_2013	The Federal Institute for Risk Assessment
10	BMEL_2014a	The Federal Ministry for Food and Agriculture
11	BMEL_2014b	The Federal Ministry for Food and Agriculture
12	BMEL_2014c	The Federal Ministry for Food and Agriculture
13	Saxony_2013a	Saxony Government
14	Saxony_2013b	Saxony Government
15	Duisburg_2013	Saxony Government
16	BFR_2014	The Federal Institute for Risk Assessment
17	Bundesrechnungshof_2014	
18	Stuttgart_2014	Stuttgart Government
19	CVUA_2014a	Chemical and Veterinary Inspection Office of Stuttgart
20	CVUA_2014b	Chemical and Veterinary Inspection Office of Stuttgart
21	CVUA_2014c	Chemical and Veterinary Inspection Office of Stuttgart
22	CVUA_2014d	Chemical and Veterinary Inspection Office of Stuttgart
EU		
23	DG SANTE_2013a	Directorate General for Food & Safety
24	DG SANTE_2014a	Directorate General for Food & Safety
25	DG SANTE_2014b	Directorate General for Food & Safety

26	DG SANTE_2014c	Directorate General for Food & Safety
27	DG SANTE_2014d	Directorate General for Food & Safety
28	EFSA_2014a	European Food Safety Authority
29	EFSA_2014b	European Food Safety Authority
30	EFSA_2014c	European Food Safety Authority
31	EFSA_2014d	European Food Safety Authority
32	EFSA_2014e	European Food Safety Authority
33	EFSA_2014f	European Food Safety Authority
34	EFSA_2014g	European Food Safety Authority
35	FVO_2013a	Food and Veterinary Office
36	FVO_2013b	Food and Veterinary Office
UK		
37	APHA_2014	Animal and Plant Health Agency
38	DEFRA_2014a	Department for Environment, Food & Rural Affairs
39	DEFRA_2014b	Department for Environment, Food & Rural Affairs
40	FSA_2013a	Food Standards Agency
41	FSA_2013b	Food Standards Agency
42	FSA_2013c	Food Standards Agency
43	FSA_2013d	Food Standards Agency
44	FSA_2013e	Food Standards Agency
45	FSA_2013f	Food Standards Agency
46	FSA_2013g	Food Standards Agency
47	FSA_2014a	Food Standards Agency
48	FCO_2014	Foreign & Commonwealth Office
49	CIEH_2014	The Chartered Institute of Environmental Health
50	Horsham_2014	Horsham local authority
51	Felixstowe_2013	Felixstowe Port
52	Heathrow_2013a	Heathrow Airport
53	Heathrow_2013b	Heathrow Airport
54	London Port Health Authority_2013	London Port Health Authority
55	Huntingdonshire_2014	Huntingdonshire local authority

56	Great Yarmouth_2014	Great Yarmouth local authority
57	Waveney & Suffolk Coastal_2014	Waveney & Suffolk Coastal local authority
58	Horsham_2014	Horsham local authority
59	Ipswich_2014	Ipswich local authority
60	Rother and Wealden_2014	Rother and Wealden local authority
61	Brighton & Hove_2014	Brighton & Hove local authority
62	Norwich_2014a	Norwich local authority
63	Norwich_2014b	Norwich local authority
Industry		
64	BLL_2014a	German Federation for Food Law and Food Science
65	BLL_2014b	German Federation for Food Law and Food Science
66	FoodDrinkEurope_2014	FoodDrinkEurope
67	IMTA_2014a	International Meat Trade Association
68	IMTA_2014b	International Meat Trade Association
69	BRC_2012	British Retail Consortium
70	Moto Hospitality_2014	Moto Hospitality